### 1 THE WESTON FIRM GREGORY S. WESTON (239944) greg@westonfirm.com 1405 Morena Blvd., Suite 201 San Diego, CA 92110 Telephone: (619) 798-2006 Facsimile: (619) 343-2789 5 **Counsel for Plaintiff** 6 7 UNITED STATES DISTRICT COURT 8 EASTERN DISTRICT OF CALIFORNIA 9 10 11 Case No: 1:21-cv-1341-DAD-JLT 12 AILEEN BROOKS, on behalf of herself and all others similarly situated, FIRST AMENDED CLASS ACTION COMPLAINT FOR 13 VIOLATIONS OF: 14 Plaintiff. THE UNFAIR COMPETITION LAW, 15 v. THE FALSE ADVERTISING LAW, AND 16 IT WORKS MARKETING, INC., THE CONSUMER LEGAL REMEDIES ACT IT WORKS! GLOBAL, INC., MARK 17 PENTECOST, and PAUL NASSIF 18 MAGISTRATE CONSENT/NO JURY DEMAND Defendants. 19 20 21 22 23 24 25 26 27 28

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Plaintiff Aileen Brooks, on behalf of herself, all others similarly situated, and the general public, by and through her undersigned counsel, hereby sues Defendants It Works Marketing, Inc., It Works! Global, Inc., Mark Pentecost, and Paul Nassif (collectively "Defendants" or "It Works"), and upon information and belief and investigation of counsel, alleges as follows:

#### T. JURISDICTION AND VENUE

- 1. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d)(2) (The Class Action Fairness Act) because the matter in controversy exceeds the sum or value of \$5,000,000 exclusive of interest and costs and because more than two-thirds of the members of the class defined herein reside in states other than the states of which Defendants are residents.
- 2. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Plaintiff Aileen Brooks suffered injuries as a result of Defendants' acts in this District; many of the acts and transactions giving rise to this action occurred in this District; and Defendants: (1) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets of this District through the distribution and sale of its products in this District, and (2) are subject to personal jurisdiction in this District.

#### II. **NATURE OF THE ACTION**

- 3. This case concerns a complex criminal conspiracy between Mark Pentecost and Paul Nassif (collectively, the "Individual Defendants") and It Works Marketing, Inc. and It Works! Global, Inc. (collectively, the Corporate Defendants") to defraud the public through the unlawful sale of illegal unapproved new drugs, which in turn are marketed through an illegal multi-level marketing scam, and which uses unlawful credit card repeat autobilling practices.
- 4. Every aspect of the company is permeated in fraud. The products make fraudulent claims. The company's "independent distributors" are enticed to push the fraudulent products on their friends and family through deceptive claims of vast commissions that do not materialize. Indeed, even the name of the company, It Works, is deceptive: the products it sells do not, in fact work.
  - 5. The FTC last year found It Works "unlawfully misrepresent[s]" its MLM programs.
- 6. The FDA has long held the very claims and ingredients sold in It Works Weight Control Drugs are not safe and effective for weight control.

- 7. The marketing and advertising of Defendants' products was intended to, and did, deceive class members into believing that Defendants' products could provide benefits akin to those which prescription drugs provide, though in truth, these products are entirely ineffective.
  - 8. Each of these products were created in furtherance of Defendants' unified conspiracy to violate the laws of California and of the United States.
  - 9. Mark Pentecost and Paul Nassif collaborated to create the "Dr. Nassif Collection" to be sold by It Works. These products, which are still sold by Pentecost and Nassif through the It Works! website and distributors, include:
    - It Works! Dr. Nassif Enhancing Lash & Brow Serum
    - It Works! Dr. Nassif Firming Neck Treatment
    - It Works! Dr. Nassif Illuminating Facial Pads
  - 10. Each of these products was created by Individual Defendants with the knowledge the claims made on the product label and advertising materials were false.
  - 11. The products were then sold by the Corporate Defendants to consumers seeking products which would provide the results touted by Defendants.
  - 12. Defendants' hooked and defrauded Plaintiff by selling her the illegal weight control drug Thermofight  $X^x$  ("Thermofight"), which they unlawfully and fraudulently call a "thermogenic weight loss formula."
  - 13. Defendants engaged in a consistent, long-term campaign to fraudulently market Thermofight as a safe and effective "fat burner" and rapid weight loss solution.
  - 14. The claims made on the Thermofight's label, website, Amazon page, and other marketing are misleading under California's Consumer Legal Remedies Act, Unfair Competition Law, and False Advertising Law. Moreover, the labeling and advertising of Thermofight also violates California's "baby FDCA" statute, also known as the Sherman Law.
  - 15. These claims are also contrary to those allowed by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDCA"), and subject any individual manufacturing or selling it to liability for the sale of an unapproved new drug.
    - 16. Defendants' misrepresentations and omissions, described in detail herein, mislead

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consumers into believing that Thermofight is a safe and effective weight control drug.

- 17. Plaintiff Aileen Brooks purchased and used Thermofight in reliance upon these deceptive claims, and with the belief that the product was sold in compliance with state and federal regulations.
- 18. Ms. Brooks used Thermofight as directed, but the product failed to deliver the advertised benefits.
- 19. Thermofight is sold as one of a suite of scam weight control drugs (collectively the "Weight Control Drugs,") including Advanced Formula Fat Fighter ("Fat Fighter"), Slimming Gummies, and Carb Control Dual Action Complex ("Carb Control").
- 20. Defendants market each of the Weight Control Drugs as safe and effective means to lose weight, reduce fat, and curb cravings.
- 21. Defendants promote the Weight Control Drugs as capable of providing benefits akin to those prescription drugs would provide, when in truth, none of the Weight Control Drugs cannot deliver the advertised benefits. Indeed, the FDA long ago found the claimed active ingredients in the Weight Control Drugs are not safe and effective for weight control. See 21 CFR § 310.545.
- 22. Defendants also manufacture, market, distribute, and sell a number of purported skin enhancement drugs under the "Dr. Nassif Collection" brand name (collectively, the "Nassif Collection").
- 23. Defendants deceptively market each product within the Nassif Collection as capable of providing benefits of FDA approved drugs.
- 24. After duping unwary consumers into purchasing their illegal unapproved drugs through the use of deceptive claims, Defendants employ unfair and illegal auto-billing practices to extract additional money from them.
- 25. Further, Defendants seek to prevent consumers from pursuing legal action against them through the use of unconscionable contracts.
- 26. This action is brought to remedy Defendants' unfair, deceptive, immoral, and unlawful conduct. On behalf of the class defined herein, Plaintiff seeks an order compelling It Works to, *inter alia*: (1) cease marketing and selling the illegal unapproved new Weight Control Drugs; (2) cease marketing the Nassif Collection as illegal unapproved new drugs; (3) conduct a corrective advertising campaign; (4) destroy all misleading and deceptive materials and products; (5) cease using unlawful auto-billing

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practices; (6) award Plaintiff and the Class members damages, punitive damages, interest, and restitution; and (7) pay costs, expenses, and attorney fees.

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#### III. **PARTIES**

- 27. Plaintiff Aileen Brooks is a resident of Bakersfield who purchased Thermofight for personal and household use during the class period defined herein.
- 28. Defendant It Works Marketing, Inc. is a Florida corporation headquartered in Palmetto, FL. It Works Marketing, Inc. manufactures, markets, distributes, and sells a number of purported weight control solutions including Thermofight, Fat Fighter, Slimming Gummies, and Carb Control. Further, It Works Marketing, Inc. manufactures, markets, distributes, and sells a number of purported skin enhancement products under the "Dr. Nassif Collection" brand name.
- 29. Defendant It Works! Global, Inc. is a Florida corporation headquartered in Palmetto, FL. It Works! Global, Inc. manufactures, markets, distributes, and sells the Weight Control Drugs. Further, It Works! Global, Inc. manufactures, markets, distributes, and sells the Nassif Collection.
- 30. Defendant Mark Pentecost is an individual who resides in Florida and is sued in his individual capacity. Pentecost is the founder and CEO of It Works Marketing, Inc. and It Works! Global, Inc. Pentecost advertises It Works to potential MLM "Independent Distributors" by engaging in highprofile conspicuous consumption, including purchasing a \$14 million private island off the coast of Florida and traveling by private jet.







- 31. At all relevant times, Pentecost has aided and abetted the manufacturing, marketing, distribution, and sale of the Weight Control Drugs and the Nassif Collection. Pentecost controls the Corporate Defendants and created them for the primary purpose of engaging in crime, in particular the sale of illegal products, the sale of fraudulent weight control and skin enhancement products, and unlawful auto-billing fraud. He runs the corporations for the primary purpose of engaging in these crimes and does not observe the corporate formalities of legitimate businesses.
- 32. Pentecost ordered, authorized, and participated in the long-term, fraudulent advertising scheme complained of herein.
  - 33. Pentecost also ordered, authorized, and participated in the unlawful auto-billing practices

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complained of herein.

- 34. Pentecost also ordered, authorized, and approved the unconscionable "Terms of Use" for Defendants' website, which unlawfully purport to (1) prevent injured consumers from pursuing public injunctive relief in any forum, (2) prevent injured consumers from seeking punitive damages, and (3) limit consumers' monetary recovery to \$100.
- 35. Paul Nassif is a plastic surgeon and reality show star who resides in Los Angeles County, California and who co-hosts the E! network shows Botched and Botched by Nature. Nassif's former wife was one of the "Real Housewives of Beverly Hills."
- 36. Nassif developed several products for the other Defendants and works as a celebrity doctor endorser, giving them the legitimacy of a product developed by a physician, though Nassif knows the products to be ineffective and fraudulently marketed.
- 37. At all relevant times, Nassif aided and abetted the advertising and sale of Defendants' products.
- 38. In addition to lending his name to an It Works product line, Nassif promoted It Works products as safe and effective in press releases and videos posted on the It Works website and social media pages.
- 39. The Individual Defendants conspired with the Corporate Defendants to engage in a long-term, fraudulent advertising campaign with the goal of positioning Defendants' products as safe and effective when in truth, the products do not deliver any of the advertised benefits.

### IV. RELEVANT BACKGROUND INFORMATION

### A. Mark Pentecost and It Works' Misleading Compensation Claims

- 40. Mark Pentecost founded It Works! in 2001 to market the "It Works! Wrap," a purported "contouring product" which Defendants claim "can tighten, tone, and firm any area of your body in as little as 45 minutes."
  - 41. Since its inception, the entire It Works! business model has been a criminal enterprise.

<sup>&</sup>lt;sup>1</sup> See https://www.itworks.com/news/it-works-global-ceo-named-entrepreneur-of-the-year/ (last visited November 2, 2021).

- 42. Defendants, at Pentecost's direction, employ a "multi-level marketing" scheme in which independent "distributors" sell It Works products both directly to consumers and to other "down the line distributors."
- 43. It Works provides its distributors with marketing materials and instructions on how to sell their ineffective unapproved new drugs on unwary consumers.
  - 44. "Independent distributors" rely on scripts written by It Works to sell Defendants' products.
- 45. Distributors receive commissions from the sale of It Works products to consumers and "down the line distributors," but only if they hit a monthly minimum sales target. Distributors who do not hit their sales targets are still required to pay for It Works products but are not paid by Defendants.
- 46. Defendants use deceptive earnings claims for attract more distributors. For example, Defendants provided prospective distributors with the following "Average Annual Distributor" chart:



These figures are taken from the 2013 it Works! Income Disclosure Statement located at www.lavorksglobal.com/ids. The earnings of any it Works! Independent Distributor contained in this chart are not necessarily representative of the income; if any, that an it Works! Independent Distributor can or will earn through participation in the it Works! Compensation Plan. These figures should not be considered as guarantees or projection of your actual earnings or profits. Success with it Works! Compensation Plan at wait, which require hard work, difference, and leadership. Your success will depend upon how effectively you exercise these qualifies. For more information, view the It Works! Compensation Plan at wait, which seems the second of your actual earnings or the property of the property of

47. However, as evidenced by the chart below, while "Ambassadors" allegedly made \$585,909

It Works!"

annually, just 0.05% (1 in 2000) of distributors reached this level in 2019. Further, 85.94% of distributors do not even reach the second level and make \$48 monthly on average. In 2019, 95.6% of distributors took home less than \$349 monthly.

### 2019 Income Disclosure Statement

						Months in Company		npany
DISTRIBUTOR PAID RANK	% of All Distributors	% of Active Distributors	Active Distributor Monthly High	Active Distributor Monthly Low	Active Distributor Monthly Average	High	Low	Average
DISTRIBUTOR	85.94%	83.50%	\$2,317	91	\$48	**	**	**
EXECUTIVE	3,31%	3.74%	\$3,410	\$3	\$240	73	1	3
RUBY	8.35%	7.52%	\$4,201	830	\$349	74	1	4
EMERALD	1.59%	1.90%	\$28,184	\$246	\$687	85	-1	9
DIAMOND	1.49%	1.76%	\$35,450	\$576	\$2,009	85	1	13
DOUBLE DIAMOND	0.83%	0.99%	\$26,779	\$1,211	\$4,485	87	1	21
TRIPLE DIAMOND	0.29%	0.35%	\$50,527	\$1,950	\$8,569	63	2	30
PRESIDENTIAL DIAMOND	0.16%	0.18%	\$53,780	\$1,130	\$13,507	92	2	43
AMRASSADOR DIAMOND	0.05%	0.07%	\$144,249	\$5,906	\$24,466	97	33	57
Total	100.00%	100.00%			\$221			

The income statistics above are reflected in US dollar amounts and exclude Distributors in Japan and Korea. Income is defined as commissions received from it. Works! and does not include income received from personal sales. "Active Distributor" is defined as a Distributor who earned at least one commission in 2019, Distributors who were inactive in 2019 did not earn commission in 2019, but had earned at least one commission prior to 2019 and had renewed their annual distributorship in 2019. The average monthly income for all Distributors (active and inactive) in 2019 was \$ \$3. Out of all Distributors that signed up as Distributors since the beginning of 2019, \$1.50 were still active at the end of the year. Months in Company is calculated by looking at every Distributor who made a new rank for the first active in 2019, and how long it took from another date to date of first active legithal arank.

- 48. In a 2015 interview, Mark Pentecost, founder and CEO, reflecting on his multi-level marketing, claimed "I think it's the greatest industry there is because the American Dream is back alive ... I was a teacher and a coach and now I'm the CEO of a multimillion dollar company."<sup>2</sup>
- 49. More recently, Defendants promoted their multi-level marketing scheme as a means to stay afloat financially during the COVID-19 pandemic. Videos posted on Defendants' web properties included deceptive earnings claims, such as:
  - "Because of It Works!, her family's income isn't impacted by COVID-19"3

<sup>&</sup>lt;sup>2</sup> Molly Mushine, *How 'It Works!' dominated Facebook and drove more than \$1 billion in sales*. BUSINESS INSIDER, Sept. 29, 2015, https://www.businessinsider.com/is-it-works-legit-2015-8 (last visted November 2, 2021).

https://www.ftc.gov/system/files/warning-letters/covid-19-letter\_to\_it\_works\_marketing\_inc.pdf (visited Nov. 2, 2021).

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- "Within six months I was making more than my government job!"
- "At the age of 29, I will become a millionaire all from my social media!" *Id.*
- "So much uncertainty in the world right now but our team is NOT struggling. We are having the biggest month EVER and it's only the 4th! sooooo many people changing their LIFE right now and are pushing to earn a \$15,000 and \$20,000 bonuses! Working from home has never been such a blessing. Does anyone else need an income working from home right now?"<sup>4</sup>
- "Can you imagine if you can take your family on dream vacations? ... People are doing it. Why not you?" *Id*.
- 50. On April 24, 2020, the FTC sent a cease-and-desist letter to Defendants relating to the earnings claims above, stating

Representations about a business opportunity, including earnings claims, violate Section 5 of the FTC Act, 15 U.S.C. § 41 et seq., if they are false, misleading, or unsubstantiated and material to consumers. Express and implied earnings claims must be truthful and nonmisleading to avoid being deceptive, which means that claims about the potential to achieve a wealthy lifestyle, career-level income, or significant income are false or misleading if business opportunity participants generally do not achieve such results. Even truthful testimonials from or about participants who do earn significant income or more will likely be misleading unless the advertising also makes clear the amount earned or lost by most participants. It Works! and your business opportunity participants and representatives must immediately cease making all express and implied earnings claims that would be false or misleading to current or prospective participants. You are responsible for the claims of your business opportunity participants and representatives . . . You are advised to review all claims relating to your business opportunity and immediately cease, and require your business opportunity participants and representatives to cease, making claims that are not supported by the evidence or substantiation described above.<sup>5</sup>

- 51. Pentecost is also directly involved with advertising of the Corporate Defendants' products. As CEO, Pentecost directly ordered, authorized, and participated in the deceptive and unlawful conduct complained of herein.
  - 52. Further, Pentecost is directly involved with Corporate Defendants' product development.
  - 53. In a 2013 interview with the Tampa Bay business journal, Pentecost noted that the "obesity

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https://www.ftc.gov/system/files/warning-letters/covid-19-letter\_to\_it\_works\_marketing\_inc.pdf (visited Nov. 2, 2021).

<sup>&</sup>lt;sup>5</sup> See Exhibit 1 hereto.

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epidemic" has "sent people on a health craze." He further stated It Works would "continue to sell as people continue to demand health products." *Id*.

- 54. At Pentecost's direction, the Corporate Defendants sought to capitalize on this trend, pushing purported Weight Control Drugs such as Thermofight, Slimming Gummies, Fat Fighter, and Carb Control.
- 55. This was part of a long-term advertising campaign with the goal of deceiving consumers into purchasing ineffective weight control supplements and skin care products.
- 56. In a September 2020 interview with Direct Selling News, Pentecost stated Defendants have "reinvented ourselves" and made claims about "Skinny Brew, a fat-burning coffee." He falsely claimed that the drugs are "results-driven products that are backed by science. The goal is to help our customers achieve results with natural ingredients, incredible flavor and a fun experience to use."
  - 57. However, as set forth below, Defendants' claims of "clinical proof" are patently false.
  - 58. In another interview, Pentecost noted that

There are some rulings lately that maybe there's some light at the end of the tunnel, but I do feel like some of the regulations have put more strain on our channel, industry than others . . . It's put more on us to be sure of our products—that we can get ingredients that we can have clinicals on. I think our product team has done a great job realizing this. There are some claims right now that we're able to say because of the clinicals. We're being very intentional.<sup>8</sup>

- 59. In a promo video, Pentecost introduces Defendant Nassif as a "highly trained facial, plastic and reconstructive surgeon from one of our favorite TV shows, Botched. He's an expert in the field of cosmetics and beauty . . . I've known this for a while, but I finally get to introduce you to Dr. Paul Nassif."
  - 60. Pentecost goes on to promote the new product line, stating, "It Works! has released an

<sup>&</sup>lt;sup>6</sup> https://www.bizjournals.com/tampabay/print-edition/2013/07/19/fast-50-2013-it-works-global.html (visited Nov. 2, 2021).

<sup>&</sup>lt;sup>7</sup> https://www.directsellingnews.com/it-works-dreams-for-a-new-season/ (visited Nov. 2, 2021).

<sup>&</sup>lt;sup>8</sup> https://www.directsellingnews.com/stuart-macmillan-talks-with-mark-pentecost-about-pivots-plansbeing-customer-centric-more/ (emphasis added) (visited Nov. 2, 2021).

<sup>&</sup>lt;sup>9</sup> https://www.facebook.com/TheOfficialItWorks/posts/519474658658808 (visited Nov. 2, 2021).

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1	exclusive col	llection of skin care products formulated by you, Dr. Paul Nassif. So thank you for
2	collaborating	with us on this incredible new products." <i>Id</i> .
3	61.	Defendants' deceptive scheme has been highly profitable—"[c]ompany revenue soared
4	from \$27 mil	lion in 2010 to \$538 million in 2014, according to numbers provided by It Works!." <sup>10</sup>
5	62.	Defendants' scheme has allowed Mark Pentecost to amass a fortune. In 2010, Pentecos
6	purchased Sto	oneybrook Golf Club in Mantee County, FL for \$3.48 million. 11 In 2015, Pentecost bought
7	his own, 104-	acre private island off the coast of Florida for \$14.5 million. 12
8	63.	Seven months later, Pentecost purchased a \$6.8 million dollar ranch in Manatee County
9	Florida. <sup>13</sup>	
10	В.	Dr. Paul Nassif
11	64.	Dr. Paul Nassif, star of the TV show "Botched," joined It Works! as a celebrity endorser
12	in 2019. <sup>14</sup>	
13	65.	Nassif partnered with It Works! to create a line a skincare products bearing his name
14	including It	Works!/Dr. Nassif Enhancing Lash & Brow Serum, It Works!/Dr. Nassif Firming Neck
15	Treatment, ar	nd It Works!/Dr. Nassif Illuminating Facial Pads.
16	66.	On the It Works! website, Defendants represent that:
17		first-ever celebrity collaboration, It Works! partnered with world-famous plastic
18		n, Dr. Nassif from the television show, <i>Botched</i> , to create an exclusive, premier re line that's targeted towards common beauty issues. Get more beautiful brows and
19		in the blink of an eye with Enhancing Lash & Brow Serum, become fresh-faced with
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22	10 Molly M	
23		SIDER, Sept. 29, 2015
24	https://www	.businessinsider.com/is-it-works-legit-2015-8 (visited Nov. 2, 2021).
25		//www.businessobserverfl.com/article/manatee-county-couple-buys-stoneybrook-golf-club. November 2, 2021).
26		s://www.news-press.com/story/money/2015/07/17/works-founder-mark-pentecost-million- nd-little-bokeelia/30269365/ (visited Nov. 2, 2021).

<sup>13</sup> https://www.bradenton.com/homes/article56699403.html (visited Nov. 2, 2021).

<sup>14</sup> https://www.youtube.com/watch?v=smdEPrjxVM0 (visited Nov. 2, 2021).

FIRST AMENDED CLASS ACTION COMPLAINT

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27 28 <sup>17</sup> https://m.facebook.com/watch/?v=527205221216055&\_rdr (visited Nov. 2, 2021).

https://www.facebook.com/TheOfficialItWorks/videos/703063090184375/ (visited Nov. 2, 2021).

<sup>19</sup> https://www.youtube.com/watch?v=BQaqwd7TwKM (visited Nov. 2, 2021).

Over time, most lashes and brows become brittle, thin and undefined. Now, both attention getting eyebrows and lashes make a huge difference in defining your face. Enhancing lash and brow serum does exactly that by strengthening and nourishing from the root. You'll get lashes and brows that look longer, lusher, fuller and replenish. 18

- In yet another video promoting the products, Nassif claims, "I'm on a TV show called Botched when our sixth season and it's airing right now across one hundred and sixty-six different countries. And if I put something together for you, I mean it."19
- 76. Nassif and Pentecost conspired with the Corporate Defendants to engage in a long-term, fraudulent advertising campaign to market Defendants' products as safe and effective, when in truth, the products fail to deliver any of the advertised benefits.

#### V. PLAINTIFF'S PURCHASE OF THERMOFIGHT

- 77. Plaintiff Aileen Brooks purchased Thermofight from an independent distributor using the It Works website on May 11, 2020. She paid \$39.95 plus shipping and handling for a total of \$48.25.
- 78. When purchasing Thermofight, Plaintiff read and relied on Defendants' representations that Thermofight is a safe and effective weight control product.
- 79. Relying on Defendants' claims, Plaintiff believed that Thermofight would boost her metabolism, burn fat, and provide rapid weight loss.
- 80. Ms. Brooks used Thermofight as directed, but the product did not deliver the advertised benefits, nor any results at all.
- 81. Because Plaintiff expected these statements to be true and honest, but they were not, she did not receive the benefit of her purchases.

### VI. THERMOFIGHT'S SPECIFIC MISREPRESENTATIONS, MATERIAL OMISSIONS,

### **AND DRUG CLAIMS**

82. During the Class Period, Defendants manufactured, advertised, and sold Thermofight in packaging bearing misleading claims relating to Thermofight's efficacy as a fat burner and rapid weight control drug. Defendants also made misleading representations relating to Thermofight's efficacy on their website and Amazon page.

83. Thermofight's label, website, and Amazon page included the following claims which are not only false and misleading, but also show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease.

### A. Thermofight's Packaging

84. An exemplar of Thermofight's packaging, purchased by Plaintiff, is as follows:

THERMOFIGHT X

NEXT GEN FAT BURN 2.0!

THERMOGENIC WEIGHT LOSS
FORMULA!

Amol	ınt Pe	r Serving	%DV
Calcium		140 mg	11%
Chromium (as chromium dinicotinate glycin	ate)	200 mcg	571%
Proprietary Green Tea Blend Greenselect® Phytosome green tea leaf/sunflower phospholipid complex and green tea leaf extract [provides min. 112.5 mg epigallocatechin-3-O-gallate (EGCG) and 62.5 mg caffeine]		437.5 mg	,
Green coffee bean extract (Coffea robusta) (provides min. 45 mg chlorogenic acids)		100 mg	y
Proprietary Thermogenic Blend Jalapeño pepper (fruit), Black pepper (fruit), ginger (root), cinnamon (bark),		75 mg	,

Other ingredients: Calcium carbonate, microcrystalline cellulose, stearic acid, croscarmellose sodium, hypromellose, silicon dioxide, magnesium stearate, spirulina (color), glycerin, hydroxypropyl cellulose.

- 85. The specific deceptive and unlawful claims made on Thermofight's packaging include:
- "Next Gen Fat Burn 2.0"

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- "Thermogenic Weight Loss Formula"
- 86. These claims suggest Thermofight is a safe and effective fat burner and weight control drug and further render Thermofight a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

### B. <u>It Works Website and Amazon Page</u>

- 87. Defendants make the follow deceptive and unlawful claims relating to on the It Works website:
  - "extraordinary impact"
  - "designed to boost your metabolism and melt away fat."
  - "contains Caffeine and Jalapeno Pepper to help you achieve and maintain an ideal fatburning mode"
  - "Fire up your thermogenic weight loss"
  - "Uses a clinically proven weight-loss ingredient that helps you lose an average of 31 pounds in 90 days!"
  - "Activates enhanced thermogenesis and boosts your energy"
  - "Accelerates ketosis by supporting rapid ketone generation"
  - "Packs powerful ingredients like Green Coffee Bean, Chromium, Jalapeno Pepper, and increased levels of Caffeine"
  - "Boosts fat, carb, macronutrient, and stored energy metabolism"
  - "Helps keep blood sugar under control and decreases sugar cravings"
  - "Supports energy levels and combats tiredness"
  - "Includes Green Tea, renowned for fat loss and nutritional properties"
  - "simple and convenient way to burn more fat—even without exercise"
  - "powering up your fat metabolism"
  - "Chromium Boosts metabolism"
- 88. These claims suggest Thermofight are a safe and effective weight control drug that can burn fat, increase energy, and provide rapid weight loss, "even without exercise." However, Thermofight does not deliver any of the advertised benefits. These claims render Thermofight an unapproved new drug within the meaning of 21 U.S.C. § 321(g)(1). Moreover, all of the It Works Weight Control Drugs contain ingredients the FDA has declared not safe and effective for weight control products, rendering them misbranded under state and federal law. See 21 CFR § 310.545

- 89. A true and correct copy of the "Product Info" webpage for Thermofight, which contains the misleading claims above and was downloaded from Defendants' website, is attached hereto as **Exhibit 2**.
- 90. Thermofight's illegal drug promotion and fraud extends to its Amazon product page. Defendants make the following deceptive representation on the Thermofight Amazon page:
  - "Activates enhanced thermogenesis and boosts your energy"
  - "Accelerates ketosis by supporting rapid ketone generation"
  - "Increased levels of Caffeine and the addition of Jalapeno Pepper to help you achieve and maintain an ideal fat-burning mode"
- 91. These claims are misleading, as Thermofight cannot deliver the advertised benefits, and further render Thermofight a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

# VII. <u>DEFENDANTS' ADVERTISING FOR THERMOFIGHT IS FALSE AND MISLEADING,</u> <u>RENDERING THE PRODUCT MISBRANDED.</u>

- 92. It is unlawful to manufacture or sell any drug that is misbranded. 21 U.S.C. § 331(a), (b), (c), & (g).
- 93. A drug is misbranded "[i]f its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1).

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

- 21 U.S.C.S. § 321(n).
  - 94. Defendants' deceptive acts render Thermofight misbranded pursuant to Cal. Health & Saf.

<sup>&</sup>lt;sup>20</sup> Under the FDCA, "'labeling' means all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). This includes websites associated with the products. *See Sandoval v. Pharmacare US, Inc.*, 730 Fed. App'x 417, 420 (9th Cir. 2018).

	Case 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 20 01 113
L	Code § 110100 (adopting all FDA labelling regulations as state regulations), § 110398 ("It is unlawfu
2	for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded."), §
3	111330 (drug label misbranded if false or misleading in any particular), and further violate Cal. Bus. &
Į.	Prof. Code § 17200 (Unfair Competition Law "Fraudulent" Prong) § 17500 (False Advertising Law) and
5	Cal. Civ. Code § 1750 (CLRA).
5	95. Because Thermofight claims to treat conditions not amenable to self-diagnosis, directions
,	are not and likely cannot be written such that a layperson can safely use this product to treat those
3	conditions. The Thermofight label therefore lacks "adequate directions for use," rendering the produc
,	mishranded 21 USC & 352(f)(1): see also 21 CER & 2015 ("'Adequate directions for use' means

96. Plaintiff used Thermofight as directed, but it failed to deliver the advertised benefits.

directions under which the layman can use a drug safely and for the purposes for which it is intended.").

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### VIII. THERMOFIGHT IS AN UNAPPROVED NEW DRUG.

- 97. "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).
- 98. Here, Thermofight is a drug because it is advertised as a product which will affect the structure or function of the body or cure, mitigate, treat, or prevent disease.
- 99. The claims on the packaging and website of Thermofight render it an unapproved new drug.
- 100. The FDA has determined that the following claims, which are similar to those Defendants make regarding Thermofight, constitute "drug claims":
  - "Our natural blend of ingredients can benefit you by . . . [s]uppressing your appetite . ..[b]oosts your metabolism ... [b]urn fat & calories ... [i]ncrease energy levels ..."21
  - "Lose up to 20 pounds in just 4 weeks . . . Promotes weight loss" *Id*.
  - "Benefits . . . appetite suppression . . . reduce bloating . . . burns fat . . . reduce inches ... potentiates weight loss ... improves metabolism'" *Id*.

<sup>&</sup>lt;sup>21</sup> https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/genesis-nutrition-ultra-slim-dba-genesis-ultra-slim-616040-08062021 (visited Nov. 2, 2021).

• "Green Tea Extract ... Green Tea's polyphenols are scientifically proven"22

- "Green Coffee Beans ... use of chlorogenic acid from green coffee bean extracts as an important inhibitor of diet-related obesity ... [and] promote significant weight loss in individuals who suffer from morbid obesity." *Id*.
- "'It is a totally natural herbal supplement for anti obesity that controls anxiety, inhibits appetite, burns fat, high cholesterol, helps with sugar levels, accelerates metabolism, eliminates toxins, reduce swelling and increase your energy.'"<sup>23</sup>
- "'How does this capsule work? . . . Appetite Control . . . Accelerates metabolism . . . Increase your energy . . . Causes satiety . . . Burn fat" *Id*.
- "'Alism: eliminates fluid retention, reduces appetite" Id.
- 101. A "new drug" is any drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1). Here, Thermofight is a "new drug" within the meaning of the FDCA because it is not generally recognized as safe and effective for the intended uses. *See* Title 21 of the Code of Federal Regulations, Chapter I, Subchapter D; 21 C.F.R. § 330.1.
- 102. "No person shall introduce or deliver for introduction into interstate commerce any new drug . . ." without approval by the FDA. 21 U.S.C § 355(a); *see also* 21 U.S.C. § 331(d).
  - 103. Defendants have not received approval from the FDA to sell Thermofight.
- 104. The sale of unapproved new drugs is illegal and dangerous. First, consumers risk purchasing and using a product that will endanger their health. Second, consumers risk purchasing a product that will not effectively treat their condition, forgoing actual treatment of that condition in lieu of an unapproved new drug which may not treat their condition. The FDA's regulatory regimen helps ensure that such products are kept away from consumers.
- 105. Defendants' failure to comply with these regulations puts consumers at risk and gives them an unfair advantage over competitors that do commit the time and expense of complying with such

<sup>&</sup>lt;sup>22</sup> https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tek-naturals-565026-02052019 (visited Nov. 2, 2021).

<sup>&</sup>lt;sup>23</sup> https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/je-dois-lavoir-llc-616016-08112021 (visited Nov. 2, 2021).

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106. Thermofight does not qualify for the reduced level of regulation applicable to certain nutrition supplement products for several reasons. The Thermofight label, website, and marketing neither describe the role of any nutrient or dietary ingredient intended to affect the structure or function in humans, characterize the documented mechanism by which any nutrient or dietary ingredient acts to maintain such structure or function, nor describes general well-being from consumption of any nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6)(A).

107. California similarly prohibits the sale of unapproved new drugs. Cal. Health & Saf. Code § 111550.

### IX. DEFENDANTS UTILIZE FAKE AMAZON REVIEWS TO PROMOTE THERMOFIGHT.

- 108. In addition to deceptively marketing Thermofight through misleading claims, It Works paid for and procured thousands of fake reviews to promote its products.
  - 109. Fake online reviews are considered to be a rapidly growing problem by the FTC.
- 110. As of April 21, 2021, It Works' Thermofight Amazon page listed a total of 289 customer reviews.
- 111. ReviewMeta is a program which collects reviews for a particular product on Amazon and uses a proprietary algorithm and statistical modeling to determine whether or not reviews are credible.
- 112. Overall, It Works' Thermofight Amazon page failed ReviewMeta's analysis, and found that 27% of the reviews provided were deemed probable frauds. Such a high percentage of unreliable reviewers suggests a campaign of fake reviews. A true and correct copy of the ReviewMeta report for the Thermofight Amazon page is attached hereto as **Exhibit 3**.

### X. SLIMMING GUMMIES SPECIFIC MISREPRESENTATIONS, MATERIAL OMISSIONS, AND DRUG CLAIMS

- As previously noted, Defendants sell a number of purported Weight Control Drugs, 113. including "Slimming Gummies," "sweet vegan treats" which, Defendants claim, will allow consumers to "shrink your waist and slim your hips."
  - 114. During the Class Period, Defendants manufactured, advertised, and sold Slimming

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Gummies in packaging bearing misleading claims relating to Slimming Gummies' efficacy as a fat burner and rapid weight loss solution. Defendants also made misleading representations relating to Slimming Gummies' efficacy on their website and Amazon page.

115. Slimming Gummies' label and the It Works website included the following claims which are not only false and misleading, but also show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease.

### A. Slimming Gummies' Packaging

116. An exemplar of Slimming Gummies packaging, is as follows:



Amount	Per Serving	%DV
Calories	10	
Total Carbohydrate	4 g	1%*
Dietary Fiber	3 g	11%*
Total Sugars	1 g	**
Includes 0 g Added Sugars		0%*
Apple cider vinegar	500 mg	**
MOROSIL® Sicilian blood orange fruit extract	200 mg	**
*The Percent Daily Values (DV) are based on a 2,000 calorie diet. **Daily value (DV) not established.		

Other Ingredients: Sc-FOS, chicory root (inulin), water, pectin, citric acid, trisodium citrate, coconut oil, paprika, natural citrus flavors, and carnauba wax.

117. The product's name, "Slimming Gummies," suggests that it is a safe and effective weight loss solution and further renders the product a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

### B. <u>It Works Website</u>

- 118. Defendants make the following deceptive and unlawful claims relating to Slimming Gummies on the It Works website<sup>24</sup> and Amazon page:
  - "Super-gummies that help your belly lose inches"
  - "Shrink your waist and slim your hips with Slimming Gummies!"

<sup>&</sup>lt;sup>24</sup> https://itworks.com/shopping/item/36402VALUE (visited Nov. 2, 2021)

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- "Enjoy these low-effort, high-reward gummies that guard against unwanted love handles and expanded waistlines."
- "With just a few Slimming Gummies each day, you can start losing stubborn, pinchable fat on your stomach and hips."
- "Formulated with Apple Cider Vinegar and a clinically proven Blood Orange poweringredient, these sweet, vegan treats will keep your confidence up while you slim down."
- "Features MOROSIL® Blood Orange extract, clinically proven to shrink waist and hip circumference by inches—even lowering Body Mass Index!"
- "Attacks fattening calories that add unwanted inches to your stomach and hips"
- "Actively shrinks bloated fat cells so you can enjoy a slimmer body"
- "Clinically Proven Ingredient MOROSIL® Blood Orange extract is clinically proven to shrink waist and hip circumference by inches!"
- "They are a powerful weight-control product, so don't eat more than four gummies a day"
- "Ever feel like everything you eat goes straight to your waist or hips? You need Slimming Gummies! These low-effort, high-reward gummies help you slim down by targeting existing fat in your midsection—particularly the pinchable fat that forms on stomachs and love handles."
- "They also minimize new fat accumulation in the same areas, so you can slow down weight gain from the start."
- "Slimming Gummies are an easy, great-tasting way to lose inches and keep them off\*\*—plus, each vegan gummy is caffeine-free, stimulant-free, has 1 g net carbs, and no added sugars."
- "Their unique formula features MOROSIL®, a clinically proven Blood Orange power-ingredient that helps shrink your waist, slim your hips, and even lower your BMI over time."
- "Slimming Gummies are uniquely formulated to target and attack fat from two directions—inhibiting lipogenesis while supporting lipolysis, which are metabolic processes your body must balance for weight management"
- "Slimming Gummies limit the build-up of new fat on your body—a process known as *Lipogenesis*"
- "As you consume extra calories, the active ingredients in Slimming Gummies help derail natural fat formation that can result in stubborn belly fat, bigger hips, and love handles."

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- "Slimming Gummies offer a clinically proven, proactive first line of defense against the lipogenic accumulation of fat!"
- "As for existing fat, Slimming Gummies also support *Lipolysis*—the breakdown and release of stored fat"
- "These super-gummies enhance lipolysis by shrinking bloated fat cells and dissolving some of the fat that's already on your body. Over time, this helps you slim down as you lose unwanted inches."
- 119. These claims suggest Slimming Gummies can reduce existing fat, prevent the accumulation of new fat, and allow consumers to "actively shrink bloated fat cells," and to "shrink" their "waist and hip circumference by inches." However, Slimming Gummies to deliver any of the advertised benefits. Further, these claims render Slimming Gummies a "drug" within the meaning of 21 U.S.C. § 321(g)(1).
- 120. A true and correct copy of the "Product Info" webpage for Slimming Gummies, which contains the misleading claims above and was downloaded from Defendants' website, is attached hereto as **Exhibit 4**.

# XI. <u>IT WORKS! CARB CONTROL SPECIFIC MISREPRESENTATIONS, MATERIAL</u> <u>OMISSIONS, AND DRUG CLAIMS</u>

- 121. During the Class Period, Defendants manufactured, advertised, and sold It Works! Carb Control ("Carb Control") in packaging bearing misleading claims relating to Carb Control's efficacy as a carbohydrate inhibitor, weight control drug, and blood glucose regulator. Defendants also made misleading representations relating to Carb Control's efficacy on their website and Amazon page.
- 122. Carb Control's label, website, and Amazon page included the following claims which are not only false and misleading, but also show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease.

### A. Carb Control's Packaging

123. An exemplar of Carb Control's packaging, is as follows:

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	t Works!			
			NTR	
			COMPLI	
DIETA	RY SUPPLE			
60 CA	PLETS	EMENT		

Amount Pe	r Serving	%DV
Calcium	32 mg	2%
Chromium (as Chromium nicotinate glycinate chelate)	100 mcg	286%
Dual-Action Carb Blocking Blend: Organic InSea2® brown seaweed extract (20% polyphenols) from Ascophyllum nodosum and Fucus vesiculosus (providing less than 37.5 mcg iodine) and White kidney bean (Phaseolus vulgaris) extract.		4
Cinnamon bark (Cinnamomum cassia) 10:1 extract	70 mg	,

Other Ingredients: Microcrystalline cellulose, dicalcium phosphate dihydrate, croscarmellose sodium, silicon dioxide, magnesium stearate (vegetable), hydroxypropyl methylcellulose, glycerin.

- 124. The specific deceptive and unlawful claims made on Carb Control's packaging include:
- "Carb Control"
- "Dual-Action Complex"
- 125. These claims suggest Carb Control is a safe and effective carbohydrate inhibitor and weight loss solution and further render Carb Control a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

### B. It Works Website and Amazon Page

- 126. Defendants make the follow deceptive and unlawful claims relating to on the It Works website:<sup>25</sup>
  - "Carb Control"
  - "Dual-Action Complex"
  - "Curb your carbs and find blood-sugar balance."
  - "Featuring results-driven ingredients, It Works! Carb Control helps control the impact of carbs on your body to reduce the accumulation of unwanted fat."

<sup>&</sup>lt;sup>25</sup> https://itworks.com/shopping/item/35000 (visited Nov. 2, 2021).

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- "It works immediately with first use, so you can worry less about hidden sugars and starches in your food and cut yourself some slack."
- "It also does double-duty by helping maintain blood-sugar balance, keeping your blood-glucose levels healthy."
- "Enjoy an indulgence and leave your carb concerns behind with It Works! Carb Control."
- "Slows and controls your body's sugar and starch digestion—from the first use"
- "Minimizes the onset of carb-induced body fat and weight gain"
- "Replaces carb-induced spikes and crashes with slower, balanced glucose absorption and level energy"
- "Features marine-sourced, organically certified InSea2®, clinically proven to control your body's response to carbs"
- "Help your body block sugars and starches† by taking one caplet 30 minutes before moderate carb meals or two caplets before heavier carb consumption."
- "That excess glucose must go somewhere, and in many cases, it ultimately converts to body fat and weight gain. It Works! Carb Control works to minimize glycemic stress."
- "Each powerful caplet, with clinically proven InSea2®, slows carb digestion and absorption in your body to lessen blood-sugar spikes."
- "You'll experience more, balanced energy and less carb-induced body fat as a result."
- "You'll experience optimal results by combining It Works! Carb Control with a healthy diet that's not regularly heavy with carbs. This product optimizes a healthy diet in which some carbs can still slip through. It also helps with an occasional indulgence!"
- "It Works! Carb Control helps catch hidden carbs in your food and drinks before they're absorbed into your body."
- "There's no waiting period it works immediately, every time."
- "Take one caplet about 30 minutes before a meal or snack with moderate carbs (sugars or starches)."
- "If your meal is expected to be carb-heavy, take two caplets but do not exceed two per day."
- "It Works! Carb Control must be taken prior to eating to catch carbs before they hit your bloodstream."
- "InSea2® Harvested by hand and organically certified from wild, brown seaweed, it's clinically proven to slow carb-to-glucose conversion"
- "Cinnamon bark extract Activates cellular support of healthy blood-glucose levels"

the misleading claims above and was downloaded from Defendants' website, is attached hereto as

Defendants make the following deceptive representation on the Carb Control Amazon page:

"Accelerates ketosis by supporting rapid ketone generation"

"Minimizes the onset of carb-induced body fat and weight gain"

further render Carb Control a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

"Slows and controls your body's sugar and starch digestion—from the first use"

"Replaces carb-induced spikes and crashes with slower, balanced glucose absorption

"Features marine-sourced, organically certified InSea2, clinically proven to control

IT WORKS! ADVANCED FORMULA FAT FIGHTER SPECIFIC

MISREPRESENTATIONS, MATERIAL OMISSIONS, AND DRUG CLAIMS

These claims are misleading, as Carb Control cannot deliver the advertised benefits, and

During the Class Period, Defendants manufactured, advertised, and sold It Works!

Carb Control's illegal drug promotion and fraud extends to its Amazon<sup>27</sup> product pages.

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Exhibit 5.<sup>26</sup>

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and level energy"

your body's response to carbs"

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<sup>26</sup> https://static.myitworks.com/productsheets/35000/35000-productinfo-en.pdf

<sup>27</sup> https://amazon.com/It-works-Works-Carb-Control/dp/B08CY876HG/

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Advanced Formula Fat Fighter ("Fat Fighter") in packaging bearing misleading claims relating to Fat

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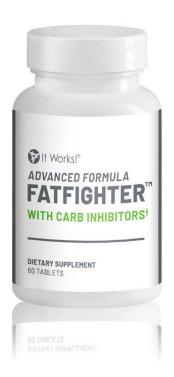
Fighter's efficacy as a fat and carbohydrate inhibitor, weight loss solution, and blood glucose regulator.

Defendants also made misleading representations relating to Fat Fighter's efficacy on their website.

132. Fat Fighter's label and webpage<sup>28</sup> included the following claims which are not only false and misleading, but also show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease.

### A. <u>Fat Fighter's Packaging</u>

133. An exemplar of Fat Fighter's packaging, is as follows:



Amount F	Per Serving	%D\				
Calcium	135 mg	10%				
Chromium (as chromium nicotinate)	150 mcg	429%				
NeOpuntia® Prickly pear cactus leaf	500 mg					
Plant-Based Metabolism Blend: 442 mg Garcinia fruit rind extract (50% hydroxycitric acid), white kidney bean extract, green tea leaf extract (50% caffeine) (providing 22 mg caffeine), banaba (Lagerstroemia speciosa) leaf extract (1% corosolic acid), gymnema leaf, bitter melon fruit, protein isolate (wheat), vanadium (as vanadyl sulfate)						

Other ingredients: Dicalcium phosphate dihydrate, microcrystalline cellulose, stearic acid, croscarmellose sodium, silica, magnesium stearate (vegetable), coating (hypromellose and glycerin)

- 134. The specific deceptive and unlawful claims made on Fat Fighter's packaging include:
- "Advanced Formula"
- "FAT FIGHTER"
- "CARB INHIBITORS"
- 135. These claims suggest Fat Fighter is a safe and effective fat and carbohydrate inhibitor as

<sup>&</sup>lt;sup>28</sup> https://itworks.com/shopping/item/30102 (visited Nov. 8, 2021).

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1	well as a weight loss solution, and further render Fat Fighter a "drug" within the meaning of 21 U.S.C	. §
2	321(g)(1).	
3	B. It Works Website	
4	136. Defendants make the follow deceptive and unlawful claims relating to Fat Fighter on the	the
5	t Works website:	
6	"Advanced Formula Fat Fighter"	
7	• "Carb Inhibitors"	
8	• "Weight & Metabolism"	
9	"Healthy Living"	
10	• "Find forgiveness from your next pizza night with Advanced Formula Fat Fighter!"	
11	<ul> <li>"Powered by NeOpuntia® from the prickly pear cactus, Advanced Formula Fat Fighter absorbs some of the fat and carbohydrates from your food so your body doesn't!"</li> </ul>	
12	<ul> <li>"Blocks some of the fat and carbs from everyday foods and drinks"</li> </ul>	
13	<ul> <li>"Helps balance healthy blood-glucose levels and reduce cravings"</li> </ul>	
14 15	• "NeOpuntia® is a vegetarian ingredient with natural fibers that have lipopholic properties, meaning they bind to fat from the foods in your stomach."	
16 17	<ul> <li>"NeOpuntia® A powerful, naturally based ingredient from the prickly pear cactus that binds to the fats from foods in your stomach to help keep them from being absorbed by your body"</li> </ul>	
18 19	• "White Kidney Bean Extract Acts as a carb inhibitor to help temper your body's starch-to-sugar digestive process"	
20	"Advanced Formula Fat Fighter with Carb Inhibitor"	
21	• "Use Advanced Formula Fat Fighter when you need a little extra help after an occasional indulgence."	
<ul><li>22</li><li>23</li></ul>	• "Simply take two tablets within 60 minutes of eating your largest meal of the day to stay guilt-free!"	
24	• "Everyone has moments of regret after the occasional fattening indulgence, but you don't have to feel guilty with Advanced Formula Fat Fighter."	
<ul><li>25</li><li>26</li></ul>	• "Take it as soon as 15 minutes after eating, and let it go to work right away – targeting fat and carbs from the food you just consumed."	
27 28	• "Its powerful formula uses active ingredient NeOpuntia® - derived from prickly pear cactus – as a vegetarian, fat-fighting ingredient that provides you with peace of mind."	

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<sup>29</sup> https://static.myitworks.com/productsheets/30102/30102-productinfo-en.pdf

- "Suppresses the effects of carbs and fats with these powerful plant-based ingredients."
- "NeOpuntia® A powerful, naturally based ingredient from the prickly pear cactus that binds fats from foods in your stomach to help keep them from being absorbed by your body"
- "White Kidney Bean Extract Acts as a carb inhibitor to help temper your body's starch-to-sugar digestive process."
- "It's a vegetarian ingredient with natural fibers that have lipopholic properties, meaning they bind to fat from the foods in your stomach."
- "As a result, some of the fat is excreted from your system naturally instead of being absorbed by your body."
- "It also contains White Kidney Bean Extract, which acts as a carb inhibitor."
- "White Kidney Bean Extract paralyzes the enzyme in your small intestine that turn starch from carbs into sugar during the digestive process."
- "This prevents the body from absorbing some of those carbohydrates, and they are also excreted naturally."
- "Because Advanced Formula Fat Fighter works in the stomach to absorb fat and in the small intestine to bloc carbs from foods you've eaten, we recommend you take one to two tablets between 15 minutes to one hour after eating your largest meal of the day., or after eating snacks with high fat-content."
- 137. These claims suggest Fat Fighter can inhibit fat and carbohydrate absorption and digestion, change the body's sugar and starch digestion, balance blood glucose levels, reduce fat accumulation by absorbing fats and carbohydrates ingested, and cause weight loss. However, Fat Fighter fails to deliver any of the advertised benefits. Further, these claims render Fat Fighter Control a "drug" within the meaning of 21 U.S.C. § 321(g)(1).
- 138. A true and correct copy of the "Product Info" webpage for Fat Fighter, which contains the misleading claims above and was downloaded from Defendants' website, is attached hereto as **Exhibit 6**.<sup>29</sup>
- 139. These claims are misleading, as Fat Fighter cannot deliver the advertised benefits, and further render Fat Fighter a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

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# XIII. <u>DR. NASSIF COLLECTION'S SPECIFIC MISREPRESENTATIONS, MATERIAL</u> <u>OMISSIONS, AND DRUG CLAIMS</u>

- 140. During the Class Period, Defendants manufactured, advertised, and sold Dr. Nassif Collection products bearing misleading claims on the products' labels and Product Information pages on the It Works! website.
- 141. The products from the Dr. Nassif Collection included the claims described below, which are not only false and misleading in violation of California's consumer protection laws, but also show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease.

### A. <u>It Works! Dr. Nassif Enhancing Lash & Brow Serum</u>

- 142. Defendants' advertising for It Works! Dr. Nassif Enhancing Lash & Brow Serum ("Enhancing Lash & Brow Serum") violates California consumer protection statutes barring false and deceptive advertising. Further, Defendants' advertising constitutes a violation of the Federal Food, Drug, and Cosmetic Act and California's Sherman Law.
- 143. **Misleading Product Information Page Claims:** Defendants manufacture, market, distribute, and sell Enhancing Lash & Brown Serum, a product which purportedly "[v]isibly improves eyelashes to appear thicker, longer, darker, and more texturized."
  - 144. However, Enhancing Lash & Brow Serum cannot deliver the advertised benefits.
- 145. By misleadingly labeling Enhancing Lash & Brow Serum as a product which will "[v]isibly improve[] eyelashes to appear thicker, longer, darker, and more texturized," Defendants imply that using Enhancing Lash & Brow Serum as directed will improve eyelashes.
- 146. This language was part of an intentional campaign to deceptively market Enhancing Lash & Brow Serum as safe and effective.
- 147. Exemplars of the Enhancing Lash & Brow Serum Product Information webpage<sup>30</sup> are as follows:

https://static.myitworks.com/productsheets/22700VALUE/22700VALUE-productinfo-en.pdf (visited Nov. 8, 2021).

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Love your lashes with Enhancing Lash & Brow Serum, exclusively created in collaboration with Dr. Nassif of *Botched* to give you captivating eyelashes and eyebrows. Featuring a formula filled with Keratin, peptides, and botanicals, Enhancing Lash & Brow Serum fortifies and nourishes your lashes and brows from their roots. See eye-catching results in less than a month with lashes and brows that look healthy, strong, and lush. It's an Enhancing Lash & Brow Serum that's more than meets the eye.

#### Features and Benefits:

- · Visibly improves eyelashes to appear thicker, longer, darker, and more texturized
- · Enhances eyebrows to look healthier, fuller, and denser
- Includes clinically proven ingredients that deliver noticeable results in less than a month
- Nourishes and conditions from the root, helping strengthen and protect against breakage
- · Uses Keratin, peptides, and botanicals to boost appearance of length and volume

#### **INGREDIENTS**

ENHANCING LASH & BROW SERUM

IT WORKS! ODR. NASSIF

Water, PEG-6 Caprylic/Capric Glycerides,
Propanediol, Glycerin, Horsetail Kelp (Laminaria
Digitata) Extract, Channeled Wrack (Pelvetia
Canaliculata) Extract, Millet (Panicum Miliaceum) Seed
Extract, Hydrolyzed Keratin (wheat), Phenoxyethanol,
Carbomer, Lecithin, Sodium Hydroxide, Propylene
Glycol, Myristoyl Pentapeptide-17, Caprylyl Glycol,
Glyceryl Caprylate, Phenylpropanol, PPG-33Buteth-45, Sodium Benzoate, Disodium EDTA,
Dipotassium EDTA, Butylene Glycol, Xanthan Gum,
Ethylhexylglycerin, Allantoin, Sorbitol, Panthenol,
Cetrimonium Chloride.

#### **DIRECTIONS**

Apply daily to the roots of your clean, makeup-free eyelashes and brows.

Caution: avoid direct contact with eye.

- 148. Additionally, Defendants' Enhancing Lash & Brow Serum Product Information page makes the following deceptive representations:
  - "Enhancing Lash & Brow Serum fortifies ad nourishes your lashes and brows from their roots."
  - "See eye-catching results in less than a month with lashes and brows that look healthy, strong, and lush."
  - "Visibly improves eyelashes to appear thicker, longer, darker, and more texturizes"
  - "Includes clinically proven ingredients that deliver noticeable results in less than a month"
  - "Nourishes and conditions the root, helping strengthen and protect against breakage"
  - "Uses Keratin, peptides, and botanicals to boost appearance of length and volume"

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- "By using Enhancing Lash & Brown Serum, you can fortify your lashes and brows to look longer, fuller, lush. And replenishes."
- "The clinically proven peptides and plant extracts in this exclusive formula provide noticeable results in less than a month, helping deliver the best lashes and brows possible."
- "Keratin A protein building block that supports healthy, lush eyelashes and eyebrows"
- "Fortifying peptides Clinically proven to enhance the appearance of thickness and length in lashes and brows"
- "Encapsulated plant extracts Clinically proven to improve the look of eyelashes with horsetail kelp, channeled wrack, and millet seed"
- "Panthenol Uses Vitamin B5 to fortify and nourish the roots of lashes and brows where growth occurs"
- 149. **Misleading Webpage Claims:** Defendants' Enhancing Lash & Brow Serum webpage<sup>31</sup> makes the deceptive following representation regarding Enhancing Lash & Brow Serum:

Longer-looking lashes and beautiful brows in the blink of an eye. Love your lashes with Enhancing Lash & Brow Serum, exclusively created in collaboration with Dr. Nassif of Botched to give you captivating eyelashes and eyebrows. Featuring a formula filled with Keratin, peptides, and botanicals, Enhancing Lash & Brow Serum fortifies and nourishes your lashes and brows from their roots. See eye-catching results in less than a month with lashes and brows that look healthy, strong, and lush.

- 150. Further, Defendants' Enhancing Lash & Brow Serum webpage makes the following deceptive representations:
  - "Visibly improves eyelashes to appear thicker, longer, darker, and more texturized"
  - "Enhances eyebrows to look healthier, fuller, and denser"
  - "Includes clinically proven ingredients that deliver noticeable results in less than a month"
  - "Nourishes and conditions from the root, helping strengthen and protect against breakage"
  - "Uses Keratin, peptides, and botanicals to boost appearance of length and volume"
  - "Fortifying peptides Clinically proven to enhance the appearance of thickness and length in lashes and brows"

<sup>&</sup>lt;sup>31</sup> Available at https://itworks.com/shopping/item/22700VALUE (visited Nov. 8, 2021).

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- "Encapsulated plant extracts Clinically proven to improve the look of eyelashes with horsetail kelp, channeled wrack, and millet seed"
- 151. These claims were part of a campaign to deceptively market Enhancing Lash & Brow Serum as a safe and effective means of enhancing the eyelashes and eyebrows, when in truth, Enhancing Lash & Brow Serum cannot deliver the promised benefits.

### B. <u>It Works! Dr. Nassif Firming Neck Treatment</u>

- 152. Defendants' advertising for It Works! Dr. Nassif Enhancing Firming Neck Treatment ("Firming Neck Treatment") violates California consumer protection statutes barring false and deceptive advertising. Further, Defendants' advertising constitutes a violation of the Federal Food, Drug, and Cosmetic Act and California's Sherman Law.
- 153. **Misleading Product Information Page Claims:** Defendants manufacture, market, distribute, and sell Firming Neck Treatment, a product which purportedly is a "fast-acting, anti-wrinkle contouring cream that actively tightens and firms the skin on your neck, jawline, and décolleté."
- 154. By misleadingly labeling Firming Neck Treatment as a product which is "fast-acting, anti-wrinkle contouring cream that actively tightens and firms the skin on your neck, jawline, and décolleté" Defendants imply that using Firming Neck Treatment as directed will improve the appearance of the skin.
- 155. This language was part of an intentional campaign to deceptively market Firming Neck Treatment as safe and effective.
  - 156. Exemplars of the Firming Neck Treatment production information page<sup>32</sup> are as follows:



Firming Neck Treatment is a fast-acting, anti-wrinkle contouring cream that actively tightens and firms the skin on your neck, jawline, and décolleté. These areas are made up of thin, delicate skin that's typically less moisturized than your face, allowing signs of aging to appear faster—until now. Developed exclusively for It Works! in collaboration with Dr. Nassif of Botched, Firming Neck Treatment should be used daily for skin that's soft, smooth, moisturized, and soothed.

#### Features and Benefits:

- · Preserves soft, youthful-looking skin on your chest and neck
- · Delivers an instant sensation of tightened and toned skin
- $\mbox{\sc Visibly}$  reduces the appearance of wrinkles, creases, and fine lines on your neck and chest
- · Creates a tighter, more contoured look to your jawline
- Moisturizes, softens, and soothes your skin to improve its texture and appearance

<sup>&</sup>lt;sup>32</sup> https://static.myitworks.com/productsheets/22800/22800-productinfo-en.pdf (visited Nov. 8, 2021).

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#### **INGREDIENTS**

Water, Glycerin, Isohexadecane, Squalane, Caprylic/ Capric Triglyceride, Propanediol, Polyglyceryl-4 Isostearate, Niacinamide, Shea Butter (Butyrospermum Parkii), Jojoba Esters, Meadowfoam (Limnanthes Alba) Seed Oil, Apricot (Prunus Armeniaca) Kernel Oil, Magnesium Sulfate, Trihydroxystearin, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Avocado (Persea Gratissima) Oil, Candelilla (Euphorbia Cerifera) Wax, Mandarin Orange (Citrus Nobilis) Peel Oil, Orange (Citrus Aurantium Dulcis) Peel Oil, Magnesium Stearate, Hydrogenated Castor Oil, Octyldodecanol, Pullulan, Octyldodecyl Xyloside, Phenoxyethanol, Sodium Dehydroacetate, Sodium Hyaluronate, Tocopheryl Acetate, C10-30 Cholesterol/Lanosterol Esters, Triethyl Citrate, Bacillus/Soybean Ferment Extract, Beeswax, Tocopherol, Bisabolol, Limonene.

#### **DIRECTIONS**

Apply Firming Neck Treatment cream onto your neck and chest twice a day.

Caution: do not use on damaged, sun-exposed, or broken skin.

- 157. Additionally, Defendants' Firming Neck Treatment Product Information page makes the following deceptive representations:
  - "Firming Neck Treatment is a fast-acting, anti-wrinkle contouring cream that actively tightens and firms the skin on your neck, jawline, and décolleté."
  - "Preserves soft, youthful-skin on your chest and neck."
  - "Delivers an instant sensation of tightened and toned skin."
  - "Visibly reduces the appearance of wrinkles, creases, and fine lines on your neck and chest."
  - "Creates a tighter, more contoured look to your jawline."
  - "Moisturizes, softens, and soothes your skin to improve its texture and appearance."
  - "To optimally achieve a fresh, firm, youthful appearance, apply Firming Neck Treatment to your neck, jawline, and upper chest twice a day."
  - "You'll experience an instant tightening effect, along with rich moisturization that helps support a softer, smoother, more refined skin texture."
  - "Firming Neck Treatment formula is specifically designed to address the appearance of loose, wrinkling skin on your neck and chest providing instant firming and tightening effects."
  - "Bioactive Marine Peptide A naturally derived marine ingredient that helps loose skin around your neck appear firmer."
  - "It's clinically proven to tighten, tone, and contour the appearance of your skin."
  - "Niacinamide A powerful, Vitamin-B3 derivative that softens and conditions your skin while firming its appearance."
  - "Pullalan A unique polysaccharide that provides an immediate tightening effect on your skin."

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<sup>33</sup> https://itworks.com/shopping/item/22800 (visited Nov. 8, 2021).

- "Delivers an instant sensation of tightened and toned skin"
- "Visibly reduces the appearance of wrinkles, creases, and fine lines on your neck and chest"
- "Creates a tighter, more contoured look to your jawline"
- "Moisturizes, softens, and soothes your skin to improve its texture and appearance"
- "Resist the onset of "tech neck" with better device positioning and with Firming Neck Treatment—to help preserve your beautiful, youthful look."
- "In a Clinical Study...95% of subjects noticed the skin on their neck and décolletage was more hydrated and less dry."
- "In a Clinical Study...72% of subjects preferred this neck cream to other neck creams they've used."
- "Clinical study on >20 women during a 3-week period using Firming Neck Treatment under the supervision of a qualified dermatologist."
- "Bioactive Marine Peptide A naturally derived marine ingredient that helps loose skin around your neck appear firmer."

"It's clinically proven to tighten, tone, and contour the appearance of your skin."

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- "Niacinamide A powerful, Vitamin-B3 derivative that softens and conditions your
- "Pullalan A unique polysaccharide that provides an immediate tightening effect on
- These claims were part of a campaign to deceptively market Firming Neck Treatment as a safe and effective means of reducing the signs of aging, when in truth, Firming Neck Treatment cannot

#### It Works! Dr. Nassif Illuminating Facial Pads

- Defendants' advertising for It Works! Dr. Nassif Illuminating Facial Pads ("Facial Pads") constitutes a violation of the Federal Food, Drug, and Cosmetic Act and California's Sherman Law.
- Misleading Product Information Page Claims: Defendants manufacture, market, distribute, and sell Facial Pads, a product which purportedly is "a gentle, effective solution for brighter skin" that "remove[s] dead skin cells and reveal a healthier, more youthful-looking complexion."
- By misleadingly labeling Facial Pads as "a gentle, effective solution for brighter skin" that "remove[s] dead skin cells and reveal a healthier, more youthful-looking complexion" Defendants imply that using Facial Pads as directed will improve the appearance of the skin.
- 164. This language was part of an intentional campaign to deceptively market Facial Pads as safe and effective.
  - Exemplars of the Illuminated Facial Pads Product Information page<sup>34</sup> are as follows: 165.



Let's face it-no one wants a lackluster complexion, and Illuminating Facial Pads are a gentle, effective solution for brighter skin. These ready-to-go exfoliation pads use both Alpha and Beta Hydroxy Acids to remove dead skin cells and reveal a healthier, more youthful-looking complexion. Formulated exclusively with Dr. Nassif of Botched, these hydrating facial pads do more than face value-they let your natural beauty shine through.

- · Uses naturally derived AHAs and BHAs to exfoliate and reduce the appearance of pores
- · Removes dead skin cells to help you achieve a brighter, fresher look and even skin-tone
- · Hydrates with humectants that naturally attract moisture to soften and refresh your skin
- · Easily wipes away oil, dirt, makeup, and dead skin that soap and water leave behind
- · Assists the natural renewal processes of your skin

<sup>34</sup> https://static.myitworks.com/productsheets/22900/22900-productinfo-en.pdf

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#### **INGREDIENTS**

Water, Witch Hazel (Hamamelis Virginiana) Water, Acetyl Glucosamine, Methyl Gluceth-20, Glycerin, Pentylene Glycol, Potassium Azeloyl Diglycinate, Bergamot (Citrus Aurantium Bergamia) Fruit Oil, Caviar Lime (Microcitrus Australasica) Fruit Extract, Chamomile (Anthemis Nobilis) Flower Oil, Damask Rose (Rosa Damascena) Flower Extract, Willow (Salix Nigra) Bark Extract, Caprylic/Capric Triglyceride, Phenoxyethanol, Polysorbate 20, Sodium PCA, Alcohol Denat., Allantoin, Potassium Sorbate, Disodium EDTA, Ethylhexylglycerin, Citric Acid, Limonene, Linalool, Citronellol, Geraniol.

#### **DIRECTIONS**

Gently wipe your face with a pad, avoiding the sensitive area around your eyes. A normal, tingling sensation may occur—do not rinse off.

Caution: do not use on dry, damaged, sun-exposed, or broken skin.

- 166. Additionally, Defendants' Facial Pads Product Information page makes the following deceptive representations:
  - "Illuminating Facial Pads are a gentle, effective solution for brighter skin."
  - "These ready-to-go exfoliation pads use both Alpha and Beta Hydroxy Acids to remove dead skin cells and reveal a healthier, more youthful-looking complexion."
  - "Uses naturally derived AHAs and BHAs to exfoliate and reduce the appearance of pores"
  - "Removes dead skin cells to help you achieve a brighter, fresher look and even skintone"
  - "Assists the natural renewal process of your skin"
  - "Exfoliation is a key part of a healthy skincare routine that makes a visible difference to your skin's appearance."
  - "By using Illuminating Facial Pads, you can revive lackluster skin so it looks fresher, younger, and healthier."
  - "Designed with premium exfoliants, these pads break down dead skin cells gently, revealing the soft, smooth, glowing skin beneath."
  - "It also primes your face for smoother makeup application and minimizes the appearance of pores."
  - "Alpha and Beta Hydroxy Acids (AHA & BHA) Beauty-boosting exfoliant acids that break down dead skin cells to reveal healthy, glowing, younger skin"
  - "Azelaic Acid Complex An advanced skin brightener that illuminates your complexion while delivering an even, balanced skin tone"
  - "Caviar Lime A gentle, skin-smoothing exfoliant that's rich in AHAs and help reveal soft, fresh skin"

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167. **Misleading Webpage Claims:** Defendants' Facial Pads webpage<sup>35</sup> makes the following deceptive representation regarding Facial Pads:

Illuminating Facial Pads are a gentle, effective solution for brighter skin. These hydrating, ready-to-go exfoliation pads use both Alpha and Beta Hydroxy Acids to remove dead skin cells and reveal a healthier, more youthful-looking complexion. Formulated exclusively with Dr. Nassif of Botched, Illuminating Facial Pads do more than face value—they let your natural beauty shine through.

- 168. Additionally, Defendants' Facial Pads webpage makes the following deceptive representations:
  - "Uses naturally derived AHAs and BHAs to exfoliate and reduce the appearance of pores"
  - "Removes dead skin cells to help you achieve a brighter, fresher look and even skintone"
  - "Hydrates with humectants that naturally attract moisture to soften and refresh your skin"
  - "Assists the natural renewal processes of your skin"
  - "My skin is smoother with fewer imperfections.' Clinical Study Participant"
  - "In a Clinical Study 95% of subjects noticed an improvement in the texture of their skin."
  - "In a Clinical Study... 95% of subjects noticed an improvement in the glow of their skin."
  - "Clinical study on >20 women during a 3-week period using Illuminating Facial Pads under the supervision of a qualified dermatologist."
  - "Alpha and Beta Hydroxy Acids (AHA & BHA) Beauty-boosting exfoliant acids that break down dead skin cells to reveal healthy, glowing, younger skin."
  - "Azelaic Acid Complex An advanced skin brightener that illuminates your complexion while delivering an even, balanced skin tone."
  - "Caviar Lime A gentle, skin-smoothing exfoliant that's rich in AHAs and helps reveal soft, fresh skin."
- 169. These claims were part of a campaign to deceptively market Facial Pads as a safe and effective means of reducing the signs of aging, when in truth, Facial Pads cannot deliver the promised

<sup>35</sup> https://itworks.com/shopping/item/22900?result=dr%20nassif%20collection (last visited November 2, 2021).

1 benefits.

# XIV. <u>DEFENDANTS' ADVERTISING FOR THE NASSIF COLLECTION IS FALSE AND</u> MISLEADING, RENDERING THE PRODUCTS MISBRANDED.

170. It is unlawful to manufacture or sell any drug that is misbranded. 21 U.S.C. § 331(a), (b), (c), & (g).

171. A drug is misbranded "[i]f its labeling is false or misleading in any particular." <sup>36</sup> 21 U.S.C. § 352(a)(1).

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C.S. § 321(n).

- 172. Defendants' deceptive acts render the Dr. Nassif Collection misbranded under Cal. Health & Saf. Code § 110100 (adopting all FDA labelling regulations as state regulations), § 110398 ("It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded."), § 111330 (drug label misbranded if false or misleading in any particular), as well as Cal. Bus. & Prof. Code § 17200 (Unfair Competition Law "Fraudulent" Prong) § 17500 (False Advertising Law) and Cal. Civ. Code § 1750 (CLRA).
- 173. Because Dr. Nassif Collection claims to treat conditions not amenable to self-diagnosis, directions are not and likely cannot be written such that a layperson can safely use this product to treat those conditions. All Dr. Nassif Collection products therefore lack "adequate directions for use," rendering the product misbranded. 21 U.S.C. § 352(f)(1); see also 21 C.F.R. § 201.5 ("Adequate directions for use' means directions under which the layman can use a drug safely and for the purposes

<sup>&</sup>lt;sup>36</sup> Under the FDCA, "'labeling' means all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). This includes websites associated with the products. *See Sandoval v. Pharmacare US, Inc.*, 730 Fed. App'x 417, 420 (9th Cir. 2018).

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for	which	it is	intended.	")

174. Defendants utilized fake clinical study claims on the Dr. Nassif Collection webpages and product information pages to mislead users.<sup>37</sup>

#### XV. ALL PRODUCTS IN THE DR. NASSIF COLLECTION ARE UNAPPROVED DRUGS.

- 175. "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1). Here, Dr. Nassif Collection products are drugs because they are advertised as a products which will affect the structure or function of the body or cure, mitigate, treat, or prevent disease.
- 176. The claims on the product information pages and webpages of all Dr. Nassif Collection products render them unapproved new drugs.
- 177. Attached hereto as **Exhibit 7** are FDA Warning Letters relating to similar claims that the FDA determined are drug claims.
- 178. A "new drug" is any drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1). Here, Dr. Nassif Collection is a "new drug" within the meaning of the FDCA because it is not generally recognized as safe and effective for the intended uses. *See* Title 21 of the Code of Federal Regulations, Chapter I, Subchapter D; 21 C.F.R. § 330.1.
- 179. "No person shall introduce or deliver for introduction into interstate commerce any new drug . . ." without approval by the FDA. 21 U.S.C § 355(a); *see also* 21 U.S.C. § 331(d).
  - 180. Defendants have not received approval from the FDA to sell Dr. Nassif Collection.
- 181. The sale of unapproved new drugs is illegal and dangerous. First, consumers risk purchasing and using a product that will endanger their health. Second, consumers risk purchasing a product that will not effectively treat their condition, forgoing actual treatment of that condition in lieu of an unapproved new drug which may not treat their condition. The FDA's regulatory regimen helps

<sup>&</sup>lt;sup>37</sup> See https://itworks.com/shopping/item/22900 (visited Nov. 8, 2021).

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ensure that such products are kept away from consumers. Defendants' failure to comply with these regulations puts consumers at risk and gives it an unfair advantage over competitors that do commit the time and expense of complying with such necessary regulations.

- 182. None of the products in the Nassif Collection qualify for the reduced level of regulation applicable to certain nutrition supplement products for several reasons. Their labels, websites, and marketing neither describe the role of any nutrient or dietary ingredient intended to affect the structure or function in humans, characterize the documented mechanism by which any nutrient or dietary ingredient acts to maintain such structure or function, nor describes general well-being from consumption of any nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6)(A).
- 183. The claims on the labels of the products in the Nassif Collection, website, and Amazon page do not relate to any classical nutrient deficiency, and Defendants do not have substantiation that their statements are truthful and not misleading pursuant to 21 U.S.C. § 343(r)(6).
- 184. California similarly prohibits the sale of unapproved new drugs. Cal. Health & Saf. Code § 111550.

### XVI. DEFENDANTS EMPLOY UNFAIR AND UNLAWFUL AUTO-BILLING PRACTICES AND "MEMBERSHIP FEES" TO EXTRACT MORE MONEY FROM CONSUMERS.

- 185. Defendants utilize unlawful and unfair auto-billing methods and charge consumers unauthorized "membership" fees to extract additional money from consumers. This illegal practice includes not just Thermofight, but a large number of other dubious products such as "slimming" gummy candy, a "Skinny Wrap" containing seaweed and green tea that supposedly makes the stomach, hips, love handles, thighs, and arms "tightened, toned, and beautifully smooth" and a "body contouring gel."
- 186. Mark Pentecost controls, directs, and actively participates in the Corporate Defendants' unfair and unlawful auto-billing scheme.
- 187. Hidden within what appears to be a normal online retail checkout is the "It Works! Loyal Customer Agreement," stating any consumer wishing to purchase any It Works! product must either (1) "make a three (3) consecutive month minimum commitment to a monthly autoshipment order," or (2) "enroll by making a \$50 Membership Fee payment." See Exhibit 8.
  - Consumers are thus forced into making "a three (3) consecutive month minimum 188.

commitment to a monthly auto-shipment order," which well exceeds the cost of the "\$50 Membership Fee payment" that Loyal Customer Agreement policy claims to offer in **Exhibit 8.** 

- 189. If a consumer receives an ineffective product from It Works! while enrolled in an auto-shipment program and wishes to cancel future shipments "prior to completing the three (3) month minimum commitment," the consumer is "charged a \$50 Membership Fee." *See* Exhibit 8.
- 190. Thus, consumers are forced to pay the \$50 Membership Fee upfront, pay for three-months' worth of ineffective products, or pay the \$50 Membership Fee to get out of their three-month commitment.
  - 191. Further, Defendants prevent class members from cancelling auto-billing.
- 192. The Better Business Bureau ("BBB") notes that It Works! "has failed to resolve underlying cause(s) of a pattern of complaints." *See* Exhibit 9. For this reason, the BBB gave It Works! a 1.75/5-star rating. "The BBB rating is based on information BBB is able to obtain about the business, including complaints received from the public." *See* Exhibit 9.

#### 193. The BBB

has received a pattern of complaints from consumers alleging that after trying to cancel with the business, they continue to receive additional products. Consumers also state that they have found additional charges being taken that the business has not informed them would be occurring. Complaints also allege that the business continues to bill after cancellation, and consumers are not informed that there is a \$50.00 cancellation fee.

#### See Exhibit 9.

- 194. As of October 8, 2021, BBB has received 139 complaints in the last 12 months about It Works!, the vast majority of which relate to the auto-billing/Membership Fee scheme described above.
  - 195. On May 26, 2021, Ellis G filed one such complaint, stating:
  - If [I] could give negative stars, best believe I would. I have just recently gone through some difficulties due to medical expenses and I notice a \$138 charge trying to go through on my account. After calling the customer service line, or sad excuse for one, they basically told me the only options are pay to cancel, or pay and still get a product. And after talking with an emotionless supervisor, I'm then told that all they can do at that point is refund me a measly \$88. THAT. IS. NOT. GOOD. ENOUGH. They need to be shut down IMMEDIATELY as they are money greedy thieves.
  - 196. On May 19, 2021, JR filed a similar complaint, stating:

This company is highly misleading. I signed up for a three month trial of Keto Coffee. You had to buy a three month subscription for a three month supply. So I tried it and paid roughly 54\$ for a months supply for three months. Turns out a months supply is 15 packets. They charge you 50\$ to cancel before the three months is over. Total scam.

197. On May 12, 2021, Rebecca S filed complaint stating:

I purchased the firming neck cream which broke me out in an itchy rash. I contacted ItWorks to get a refund or credit. They told me that they don't guarantee their products or offer a money back guarantee. I also was told that I can't cancel my autoship before my 3rd shipment or I'll have to pay a \$50 fee. I'm very disappointed and will not order any more products from this company.

198. Similarly, on March 22, 2021, Teresa K complained:

My husband and I tried the Slimming gummies. They did not work. We actually gained weight. It was only a few pounds but still was not what we bought the gummies for to lose weight. Went to cancel the autoship and was notified my card would be charged the \$50, well okay. As stated in another review, will pay the \$50 for a product that doesn't work. Will never use anything from ITWORKS!! again. Thank you for your time. WISH I COULD GIVE THIS COMPANY A ZERO STAR.

- 199. It Works! utilizes these unfair auto-billing practices and "Membership Fees" to extract every penny possible from consumers.
- 200. Plaintiff was similarly enrolled in an auto-shipment program without knowledge of her enrollment.
- 201. When making her initial purchase, Ms. Brooks was not made aware that she had been signed up for the It Works! Loyal Costumer Membership, any terms of agreement, the auto-shipment policy, or fees relating to the membership and cancellation. Ms. Brooks did not receive any of this information until after her purchase of Thermofight was complete.
- 202. Defendants did not alert Plaintiff that she was fraudulently signed up for It Works! Loyal Customer Membership, which requires a minimum auto-shipment agreement of three purchases of Thermofight, prior to her initial purchase of the product.
- 203. In fact, she did not know that she was enrolled in an auto-shipment program until she saw additional charges on her credit card statement and contacted Defendants' customer service line.
- 204. Plaintiff was charged for two months' worth of Thermofight before she realized that she was fraudulently enrolled in an auto-shipment agreement.

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1	205. When Ms. Brooks called the Corporate Defendants' customer service line to cancel future
2	shipments and request a refund, she was able to cancel future shipments, but her request for a refund was
3	denied.
4	206. Defendant's auto-billing practices constitute an "automatic renewal" as defined by Cal.
5	Bus. & Prof. Code § 17601(a).
6	207. The It Works! Loyal Customer Agreement" is an "automatic renewal offer" as defined
7	by Cal. Bus. & Prof. Code § 17601(b).
8	208. Defendants' auto-billing practices violate Cal. Bus. & Prof. Code § 17602(a) because the
9	It Works! Loyal Customer Agreement
10	fail[s] to present the automatic renewal offer terms or continuous service offer terms in a
11	<b>clear and conspicuous manner</b> before the subscription or purchasing agreement is fulfilled and in visual proximity, or in the case of an offer conveyed by voice, in temporal
12	proximity, to the request for consent to the offer.
13	209. Specifically, the auto-billing provisions in the It Works! Loyal Customer Agreement are
14	not "clearly and conspicuously" disclosed because they are not set forth
15	in larger type than the surrounding text, or in contrasting type, font, or color to the
16	surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks, in a manner that clearly calls attention to the language.
17	Cal. Bus. & Prof. Code § 17601(c)
18	210. Rather, the auto-renewal offer terms appear in the same font size and typeface as the rest
19	of the Loyal Customer Service Agreement.
20	211. Though the auto-renewal offer terms are not "clearly and conspicuously" disclosed in the
21	Loyal Customer Agreement as required, other terms within the Agreement are "clearly and
22	conspicuously" disclosed.
23	212. For example, the following provision from the Agreement is set forth in bolded font and
24	all capital letters:
25	PLEASE NOTE: LOYAL CUSTOMERS MAY PURCHASE PRODUCT FOR
26	PERSONAL USE ONLY AND MAY NOT RESELL THE PRODUCT FOR ANY REASON. ONLY IT WORKS! INDEPENDENT DISTRIBUTORS ARE

<sup>38</sup> **Exhibit 8** hereto.

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AUTHORIZED TO SELL IT WORKS! PRODUCTS. ANYONE OTHER THAN A CURRENT IT WORKS! INDEPENDENT DISTRIBUTOR FOUND TO BE SELLING OR ADVERTISING IT WORKS! PRODUCTS WILL IMMEDIATELY HAVE THEIR RIGHTS TO BUY PRODUCTS TERMINATED.

Exhibit 8 (Loyal Customer Agreement).

- 213. Provisions relating to Defendants' auto-billing practices, in contrast, are not set forth in all capital letters, nor are they bolded. *See* **Exhibit 8** (Loyal Customer Agreement).
  - 214. Defendants also violate Cal. Bus. & Prof Code § 17602(b) because they

Charge the consumer's credit or debit card, or the consumer's account with a third party, for an automatic renewal or continuous service without first obtaining the consumer's affirmative consent to the agreement containing the automatic renewal offer terms or continuous service offer terms, including the terms of an automatic renewal offer or continuous service offer that is made at a promotional or discounted price for a limited period of time.

- 215. In Ms. Brooks' case, she did not know she was being continually charged until she saw the charge for a second bottle of Thermofight on her credit card statement.
- 216. Defendants also violate Cal. Bus. & Prof Code § 17602(c) because "consumer[s] who accept[]" Defendants' "automatic renewal or continuous service offer online" are not "allowed to terminate the automatic renewal or continuous service exclusively online, which may include a termination email formatted and provided by the business that a consumer can send to the business without additional information."
- 217. In Ms. Brooks case, she was required to call Defendants' customer service department in order to cancel her auto-renewal.
- 218. When Ms. Brooks called the Corporate Defendants' customer service line, she was able to cancel future shipments, but was not refunded any of the money she had already paid to Defendants.

# XVII. <u>DEFENDANTS UNLAWFULLY ATTEMPT TO LIMIT THEIR LIABILITY THROUGH</u> <u>UNCONSCIONABLE PROVISIONS IN A CONTRACT.</u>

- 219. Pursuant to Cal. Civ. Code § 1770(a)(19), "inserting an unconscionable provision into a contract" is unlawful.
- 220. Defendants' seek to enjoin consumers from pursuing claims against them by inserting unconscionable provisions into the contract which Defendants' claim governs the claims at issue here.

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not conspicuous to a consumer using the website.

The contract at issue, the "Terms of Use" (Exhibit 10 hereto) for Defendants' website, is

- 222. The document is not displayed at any point during the checkout process, and reasonable consumers would have no reason to view it.
- The link to Defendants' "Terms of Use" appears in the bottom of each page on Defendants' website.
- 224. The link for the "Terms of Use" appears in very small font, while links to product pages, the pages describing how to become a "Loyal Customer" or distributor, pages describing the company's history and philosophy, and customer support page, among other links, appear in a much larger font above the link for the "Terms of Use."
- The link is not highlighted, bolded, or made more conspicuous than other links on the page with special text or script such that it would draw a reasonable consumer's attention.
- 226. Additionally, consumers can complete a purchase without clicking the "Terms of Use" link, and at no point during the check-out process are consumers directed to view the "Terms of Use."
- 227. In contrast, consumers are required to view and consent to other agreements during the check-out process, including Defendants' "Loyal Customer Agreement," which relates to Defendants' shipping and refund policies.
  - In addition to being inconspicuous, Defendants' "Terms of Use" are unconscionable. 228.
- 229. Specifically, the "Terms of Use" purport to waive consumers' right to seek injunctive relief in any forum:

TO THE EXTENT PERMITTED BY LAW, YOU AGREE THAT IN THE EVENT YOU INCUR ANY DAMAGES, LOSSES OR INJURIES THAT ARISE OUT OF IT WORKS!' ACTS OR OMISSIONS, THE DAMAGES, IF ANY, CAUSED TO YOU ARE NOT IRREPARABLE OR SUFFICIENT TO ENTITLE YOU TO AN INJUNCTION PREVENTING ANY EXPLOITATION OF ANY WEBSITE, SERVICE, PROPERTY, PRODUCT OR OTHER CONTENT OWNED OR CONTROLLED BY THE IT WORKS! PARTIES, AND YOU WILL HAVE NO RIGHTS TO **ENJOIN** OR RESTRAIN THE DEVELOPMENT, PRODUCTION. DISTRIBUTION, ADVERTISING, EXHIBITION OR EXPLOITATION OF ANY WEBSITE, PROPERTY, PRODUCT, SERVICE, OR OTHER CONTENT OWNED OR CONTROLLED BY THE IT WORKS! PARTIES.

Exhibit 10 (Terms of Use).

- 230. Further, the "Terms of Use" contain an unconscionable choice of law provision stating that all claims brought in relation to a purchase of Defendants' products are governed by Florida law.
- 231. While California's CLRA provides for punitive damages, Florida's Deceptive and Unfair Trade Practices does not.
- 232. Cal. Civ. Code § 1751 includes an express anti-waiver provision stating that '[a]ny waiver by a consumer of the provisions of this title is contrary to public policy and shall be unenforceable and void." *Id*.
- 233. The choice of law provision in Defendants' "Terms of Use" thus violates Cal. Civ. Code § 1751 in that the choice of law provision constitutes a waiver by a consumer and is unenforceable.
- 234. Cal. Civ. Code § 3513 provides "a law established for a public reason cannot be contravened by a private agreement."
- 235. Further, Defendants' Terms of Use purport to limit consumer's monetary recovery against Defendants to \$100:

IN NO EVENT WILL THE IT WORKS! PARTIES BE LIABLE TO YOU OR ANYONE ELSE FOR LOSS, DAMAGE OR INJURY, INCLUDING, WITHOUT LIMITATION, DEATH OR PERSONAL INJURY. IN NO EVENT WILL THE IT WORKS! PARTIES TOTAL LIABILITY TO YOU FOR ALL DAMAGES, LOSSES OR CAUSES OR ACTION EXCEED ONE HUNDRED UNITED STATES DOLLARS (\$100.00)

- 236. California's consumer protection statutes place no such limit on recovery, and the provisions in the Terms of Use which limit recovery contravene fundamental public policies.
- 237. Defendants' "Terms of Use" thus violate Cal. Civ. Code § 3513 in that they contravene Cal. Civ. Code § 1750 *et seq.*, which was established for a public reason.
- 238. Specifically, the "Terms of Use" unlawfully curtail consumers' rights under the UCL, CLRA, and FAL by (1) waiving consumers' rights to seek injunctive relief in any forum, (2) limiting consumers' remedies to claims brough under Florida law, which does not provide for punitive damages, and (3) limiting consumer's monetary recovery to \$100.
- 239. Plaintiff seeks an order declaring Defendants' "Terms of Use" to be void and an order enjoining Defendants from engaging in the unlawful practices described above.

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#### XVIII. DEFENDANTS' PRACTICES ARE "UNFAIR" WITHIN THE MEANING OF THE **CALIFORNIA UNFAIR COMPETITION LAW.**

- 240. Defendants' practices as described herein are "unfair" within the meaning of the California Unfair Competition Law because their conduct is immoral, unethical, unscrupulous, and substantially injurious to consumers, and the utility of this conduct to Defendants does not outweigh the gravity of the harm to Defendants' victims.
- 241. In particular, while Defendants' use of a long-term fraudulent advertising campaign to market unlawful products may have had some utility to Defendants in that it allows them to realize higher profit margins than if they did not use fraudulent advertising tactics, this utility is small and far outweighed by the gravity of the economic harm Defendants inflicts upon consumers. Further, the injury to consumers from Defendants' practices is substantial, not outweighed by benefits to consumers or competition, and not an injury that consumers themselves could reasonably have avoided.
- 242. Additionally, while Defendants' practice of enrolling consumers in auto-billing programs without complying with Cal. Bus. & Prof Code § 17600 et seq. may have had some utility to Defendants in the form of increase profits, this utility is small and far outweighed by the gravity of the economic harm Defendants inflicts upon consumers. Further, the injury to consumers from Defendants' practices is substantial, not outweighed by benefits to consumers or competition, and not an injury that consumers themselves could reasonably have avoided.
- Further, Defendants' use of unconscionable contracts to abridge consumers' rights to pursue claims against them is immoral, unethical, unscrupulous, and substantially injurious to consumers, and the utility of this conduct to Defendants does not outweigh the gravity of the harm to Defendants' victims.

### XIX. <u>DEFENDANTS' PRACTICES ARE "UNLAWFUL" UNDER THE UNFAIR</u> **COMPETITION LAW.**

244. Defendants' practices as described herein are "unlawful" within the meaning of the California Unfair Competition Law because the marketing, sale, and distribution Thermofight, the Weight Control Drugs, and the Nassif Collection violates the Federal Food, Drug, and Cosmetic Act, as well as California's Sherman Food, Drug, and Cosmetic Law.

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- 245. Defendants' conduct described herein is "unlawful" because it violated the following portions of the Federal Food, Drug, and Cosmetic Act ("FDCA"):
  - 21 U.S.C. § 331(a), prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded";
  - 21 U.S.C. § 331(b), prohibiting the "adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce";
  - 21 U.S.C. § 352(f)(1), requiring drugs to have adequate directions for use
  - 21 U.S.C. § 355(a), prohibiting the sale of unapproved new drugs.
- 246. Defendants' conduct described herein also violates multiple provisions of California law including, *inter alia*:
  - Cal. Health & Saf. Code § 110100 et seq., which adopts all FDA labeling regulations as state regulations;
  - Cal. Health & Saf. Code § 111330, "Any drug or device is misbranded if its labeling is false or misleading in any particular.";
  - Cal. Health & Saf. Code § 110398, "It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.";
  - Cal. Health & Saf. Code § 111440, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.";
  - Cal. Health & Saf. Code § 111445, "It is unlawful for any person to misbrand any drug or device.";
  - Cal. Health & Saf. Code § 111450, "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.";
  - Cal. Health & Saf. Code § 111550, prohibiting sale of new drug unless approved under 21 U.S.C. § 355;
  - Cal. Civ. Code § 3513, providing "a law established for a public reason cannot be contravened by a private agreement";
  - Cal. Civ. Code § 1751, providing contracts which waive consumer's rights under the CLRA are void;
  - Cal. Civ. Code § 1770(a), prohibiting misleading practices in relation to the sale of goods;
  - Cal. Bus. & Prof. Code § 17500 et seq., prohibiting false or misleading advertising;

• Cal. Bus. & Prof. Code § 17200 et seq., prohibiting fraudulent business activity.

- 247. The fraudulent marketing and advertising of the Weight Control Drugs constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.
- 248. Defendants' practices are further unlawful because Defendants "insert[ed] an unconscionable provision in [a] contract" in violation of Cal. Civ. Code § 1770(a)(19). Specifically, the "Terms of Use" for the It Works website include multiple unconscionable provisions, such as those precluding consumers from seeking injunctive relief, limiting the monetary relief consumers might obtain in the event of a dispute, and the choice of law provision stating that all claims will be governed by Florida law, among others. *See* **Exhibit 10** (It Works website "Terms of Use").
- 249. Defendants' practices are further unlawful because they violate Cal. Bus. & Prof. Code § 17602(a), as the It Works Loyal Customer Agreement constitutes an "auto-renewal offer" within the meaning of Cal. Bus. & Prof. Code § 17601, but the terms of the offer are not "clearly and conspicuously" in "larger type than the surrounding text, or in contrasting type, font, or color to the surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks, in a manner that clearly calls attention to the language."
  - 250. Defendants' practices also violate Cal. Bus. & Prof. Code § 17602(b) because Defendants Charge the consumer's credit or debit card, or the consumer's account with a third party, for an automatic renewal or continuous service without first obtaining the consumer's affirmative consent to the agreement containing the automatic renewal offer terms or continuous service offer terms, including the terms of an automatic renewal offer or continuous service offer that is made at a promotional or discounted price for a limited period of time.
- 251. Defendants also violate Cal. Bus. & Prof Code § 17602(c) because "consumer[s] who accept[]" Defendants' "automatic renewal or continuous service offer online" are not "allowed to terminate the automatic renewal or continuous service exclusively online, which may include a termination email formatted and provided by the business that a consumer can send to the business without additional information."
- 252. Defendants' unlawful acts allowed it to sell more units of the Thermofight, the Weight Control Drugs, and the Nassif Collection than it would have otherwise, and at a higher price and higher margin.

- 253. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and to commence a corrective advertising campaign.
- 254. Plaintiff also seeks an order for the disgorgement and restitution of all revenue received by Defendants from the sale of Collagen Peptides.

#### XX. <u>RELIANCE AND INJURY</u>

- 255. When purchasing Thermofight, Plaintiff was seeking products of particular qualities, including a product that safely and effectively boost her metabolism, burn fat, control blood sugar levels, and provide rapid weight loss.
- 256. Plaintiff read and relied on, for her Thermofight purchase, the product's packaging and the misrepresentations made by It Works on Defendants' website and the efficacy messages they conveyed, which were substantial factors in her purchase.
- 257. Plaintiff further relied on the reviews posted on It Works' Thermofight product page, many of which were fake or altered.
- 258. Plaintiff purchased Thermofight believing it had the qualities she sought based on the product's deceptive labeling and website and the natural assumption that products sold in stores and online by large companies would deliver advertised benefits, such as those touted on the packaging of Thermofight. The purchased product was instead unsatisfactory to her for the reasons described herein.
- 259. Plaintiff purchased Thermofight instead of competing products based on the false statements and misrepresentations described herein.
- 260. Plaintiff suffered economic injury when she purchased Thermofight because it did not provide the advertised benefits, and she would not have purchased it absent Defendants' unlawful conduct.
- 261. Thermofight was offered for sale in violation of California and federal law and has a value of \$0 because it is both illegal and ineffective.
- 262. Plaintiff would not have purchased Thermofight had she known that it was entirely ineffective and offered for sale in violation of California and federal law.
  - 263. When Plaintiff purchased Thermofight, she was unaware that she would be subject to

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Defendants' unlawful auto-renewal practices described herein.

264. Had Ms. Brooks known that Defendants would utilize these unfair and unlawful autorenewal practices to extract additional money from her, she would not have purchased Thermofight.

#### XXI. CLASS ACTION ALLEGATIONS

- 265. Plaintiff brings this action on behalf of herself and all others similarly situated (the "Class"), excluding Defendants' officers, directors, and employees, and the Court, its officers, and its families.
  - 266. The Weight Control Drugs Class is defined as follows:

All individuals who purchased Thermofight, Slimming Gummies, Carb Control, and/or Fat Fighter in the United States for their own personal or household use, and not for resale, from September 1, 2017 to the present.

267. The Automatic Billing Class is defined as follows:

All individuals Defendants charged under their automatic renewal program in the United States from September 1, 2017 to the present.

- 268. Questions of law and fact common to Plaintiff and the Classes include:
- a) Whether Defendants communicated efficacy messages through the Weight Control Drugs' labeling, packaging, and website;
- b) Whether those messages were material, or likely to be material, to a reasonable consumer;
- c) Whether those messages were false, at variance with the truth, misleading, likely to deceive, and/or had the capacity to deceive the public and/or a reasonable consumer;
- d) Whether Defendants' conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers;
- e) Whether is the Weight Control Drugs are unapproved new drugs;
- f) Whether the slight utility Defendants realize as a result of their deceptive and unlawful conduct outweighs the gravity of the harm the conduct causes to its victims;
- g) Whether Defendants' conduct violated public policy as declared by specific constitutional, statutory, or regulatory provisions;
- h) Whether the injury to consumers from Defendants' practices is substantial;
- i) Whether Defendants fraudulently omitted material information in advertising the Weight Control

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Drugs as safe and effective;

- j) Whether Defendants sold and distributed the Weight Control Drugs to the public in misleading packaging that was likely to deceive the public;
- k) Whether the Classes are entitled to restitution and attorneys' fees and costs, injunctive, and/or any other relief;
- 1) Whether Defendants' conduct was knowing, or whether Defendants reasonably should have known of the conduct;
- m) Whether Defendants' conduct constitutes violations of the California's False Advertising Law;
- n) Whether Defendants' conduct constitutes a violation of the unlawful prong of California's Unfair Competition Law;
- o) Whether Defendants' conduct constitutes violations of the California's CLRA;
- p) Whether Defendants acted willfully, recklessly, negligently, or with gross negligence in violation of the law as alleged herein;
- q) Whether any applicable statute of limitations should be tolled on behalf of the Class;
- r) Whether members of the Class are entitled to restitution and, if so, the correct measure of restitution;
- s) Whether members of the Class are entitled to an injunction and, if so, its terms; and
- t) Whether members of the Class are entitled to any further relief.
- 269. By purchasing the Weight Control Drugs, all Weight Control Drug Class members were subjected to the same wrongful conduct.
- 270. Absent Defendants' material deceptions, misstatements, and omissions, and unlawful sale, distribution, and marketing of the Weight Control Drugs, Plaintiff and other Class members would not have purchased the Weight Control Drugs.
- 271. Because all Automatic Billing Class members were enrolled in an unlawful and unfair autorenewal program, they were all subjected to the same wrongful conduct.
- 272. Plaintiff's claims are typical of the Weight Control Drugs Class's claims and the Automatic Billing Class's claims.
  - 273. All Weight Control Drugs Class members were subjected to the same economic harm when

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1	they purchased the Weight Control Drugs and suffered economic injury.
2	274. All Automatic Billing Class members were subjected to the same economic harm when
3	they were unlawfully enrolled in Defendants' auto-billing program.
4	275. Plaintiff will fairly and adequately protect the interests of the Classes, has no interests that
5	are incompatible with the interests of the Classes, and has retained counsel competent and experienced
6	in class litigation.
7	276. The Weight Control Drugs Class is sufficiently numerous, as it includes thousands of
8	individuals who purchased the Weight Control Drugs during the Class Period.
9	277. The Automatic Billing Class is sufficiently numerous, as it includes thousands of
10	individuals who purchased Defendants' products and were enrolled in an unfair and unlawful auto-
11	renewal program during the Class Period.
12	278. Class representation is superior to other options for the resolution of the controversy. The
13	relief sought for each Class member is small, as little as \$50 for some Class members. Absent the
14	availability of class action procedures, it would be infeasible for Class members to redress the wrongs
15	done to them.
16	279. Defendants have acted on grounds applicable to the Classes, thereby making final
17	injunctive relief or declaratory relief appropriate concerning the Classes as a whole.
18	280. Questions of law and fact common to the Classes predominate over any questions affecting
19	only individual members.
20	XXII. CAUSES OF ACTION
21	First Cause of Action
22	California Unfair Competition Law, Unlawful Prong
23	Cal. Bus. & Prof. Code §§ 17200, et seq.
24	281. In this and every cause of action, Plaintiff realleges and incorporates the preceding
25	allegations as if fully set forth herein.
26	282. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as
27	alleged herein constitute "unlawful" business acts and practices in that Defendants' conduct violates the

California False Advertising Law, and the California Consumer Legal Remedies Act, as alleged herein.

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	283.	All of	the It W	orks! W	/eight	Contro	ol Drugs	s conta	in ing	redie	nts the	FDA	has	declare	d not
safe a	and effe	ctive fo	r weight	control	produ	cts, re	ndering	them	misbr	andec	l unde	r state	and	federal	law.
See 2	1 CFR §	§ 310.5	45												
	20.4	ъс	1 , 1	1	C .1	44 1	C 199 1	ı	., .	1 . 1	1.1 C	11 .		,•	C .1

- 284. Defendants' conduct is further "unlawful" because it violated the following portions of the Federal Food, Drug, and Cosmetic Act ("FDCA"):
  - 21 U.S.C. § 331(a), prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded";
  - 21 U.S.C. § 331(b), prohibiting the "adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce";
  - 21 U.S.C. § 352(f)(1), requiring drugs to have adequate directions for use;
  - 21 U.S.C. § 355(a), prohibiting the sale of unapproved new drugs.
  - 285. Defendants' conduct also violates other provisions of California law including, inter alia:
  - Cal. Health & Saf. Code § 110100 et seq., which adopts all FDA regulations as state regulations;
  - Cal. Health & Saf. Code § 111330, "Any drug or device is misbranded if its labeling is false or misleading in any particular.";
  - Cal. Health & Saf. Code § 110398, "It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.";
  - Cal. Health & Saf. Code § 111440, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.";
  - Cal. Health & Saf. Code § 111445, "It is unlawful for any person to misbrand any drug or device.";
  - Cal. Health & Saf. Code § 111450, "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.";
  - Cal. Health & Saf. Code § 111550, prohibiting sale of new drug unless approved under 21 U.S.C. § 355;
  - Cal. Civ. Code § 3513, providing "a law established for a public reason cannot be contravened by a private agreement";
  - Cal. Civ. Code § 1751, providing contracts which waive consumer's rights under the CLRA are void;
  - Cal. Civ. Code § 1770(a), prohibiting misleading practices in relation to the sale of goods;
  - Cal. Bus. & Prof. Code § 17500 et seq., prohibiting false or misleading advertising; and

- Cal. Bus. & Prof. Code § 17200 et seq., prohibiting fraudulent business activity.
- 286. The challenged labeling and website statements made by Defendants thus constituted violations of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.
- 287. Defendants leveraged their deception to induce Plaintiff and members of the Class to purchase products that were of lesser value and quality than advertised.
- 288. The fraudulent marketing of the Weight Control Drugs described herein constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.
- 289. Had Plaintiff known that Thermofight was offered for sale in violation of California and federal regulations, she would not have purchased it.
- 290. Plaintiff suffered injury in fact and lost money or property as a result of Defendants' deceptive advertising: she was denied the benefit of the bargain when she decided to purchase Thermofight over competing products, which are legal, less expensive, and do not make misleading or false drug claims on their packaging.
- 291. Defendants' practices are further unlawful because they violate Cal. Bus. & Prof. Code § 17602(a) because the It Works Loyal Customer Agreement constitutes an "auto-renewal offer" within the meaning of Cal. Bus. & Prof. Code § 17601, but the terms of the offer are not "clearly and conspicuously" in "larger type than the surrounding text, or in contrasting type, font, or color to the surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks, in a manner that clearly calls attention to the language."
  - 292. Defendants' practices also violate Cal. Bus. & Prof. Code § 17602(b) because Defendants [c]harge the consumer's credit or debit card, or the consumer's account with a third party, for an automatic renewal or continuous service without first obtaining the consumer's affirmative consent to the agreement containing the automatic renewal offer terms or continuous service offer terms, including the terms of an automatic renewal offer or continuous service offer that is made at a promotional or discounted price for a limited period of time.
- 293. Defendants also violate Cal. Bus. & Prof Code § 17602(c) because "consumer[s] who accept[]" Defendants' "automatic renewal or continuous service offer online" are not "allowed to terminate the automatic renewal or continuous service exclusively online, which may include a termination email formatted and provided by the business that a consumer can send to the business

294. Defendants' unlawful acts allowed it to sell more units of the Weight Control Drugs and other auto-billed products than it would have otherwise, and at a higher price, and higher margin.

295. Had Plaintiff been aware of Defendants' false and misleading advertising tactics and unlawful auto-billing practices, and unlawful contract provisions, she would not have purchased Thermofight, and had Defendants not advertised it in a fraudulent manner, Plaintiff would have paid less for it.

#### **Second Cause of Action**

#### California Unfair Competition Law, Fraudulent Prong

Cal. Bus. & Prof. Code §§ 17200, et seq.

- 296. Cal. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."
- 297. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "fraudulent" business acts and practices in that Defendants' conduct has a likelihood, capacity or tendency to deceive Plaintiff, the Class, and the general public.
- 298. Defendants leveraged their deception to induce Plaintiff and members of the Class to purchase products that were of lesser value and quality than advertised.
- 299. Plaintiff suffered injury in fact and lost money or property as a result of Defendants' deceptive advertising: she was denied the benefit of the bargain when she decided to purchase Thermofight over competing products, which are legal, less expensive, and do not make misleading or false drug claims on their packaging.
- 300. Had Plaintiff been aware of Defendants' false and misleading advertising tactics, she would not have purchased Thermofight, and had Defendants not advertised it in a fraudulent manner, Plaintiff would have paid less for it.
- 301. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendants to commence a corrective advertising campaign; and awarding the class restitution of all monies from the sale of the Weight Control Drugs.

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#### **Third Cause of Action**

#### California Unfair Competition Law, Unfair Prong

Cal. Bus. & Prof. Code §§ 17200, et seq.

- 302. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "unfair" business acts and practices because Defendants' conduct is:
  - immoral, unethical, unscrupulous, and offends public policy;
  - the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct; and
  - the injury to consumers caused by Defendants' conduct is substantial, not outweighed by any countervailing benefits to consumers or competition, and not one that consumers themselves could reasonably have avoided.
- 303. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendants to commence a corrective advertising campaign; and awarding the class restitution of all monies from the sale of Thermofight.

#### **Fourth Cause of Action**

#### California False Advertising Law

#### Cal. Bus. & Prof. Code §§ 17500, et seq.

- 304. In violation of Cal. Bus. & Prof. Code §§ 17500 *et seq.*, the advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of Thermofight without the knowledge that the products make misleading and unapproved claims.
- 305. Defendants knew and reasonably should have known that the claims made on Thermofight's label, packaging, and website were untrue and misleading.
- 306. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendants were unjustly enriched.
- 307. In accordance with Cal. Bus. & Prof. Code § 17535, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendants to commence a corrective advertising campaign; awarding Plaintiff and

the class restitution of all monies from the sale of Thermofight in an amount of \$5 million or a greater amount to be proven at trial, actual and punitive damages, and interest to Plaintiff, an incentive award to Plaintiff in conjunction with a class award or injunction, and for attorney fees and costs to be awarded by the Court in accordance with applicable law, including the Private Attorney General Statute.

#### **Fifth Cause of Action**

#### California Consumer Legal Remedies Act

Cal. Civ. & Prof. Code §§ 1750, et seq.

- 308. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.
- 309. Defendants' policies, acts and practices were designed to, and did, result in the purchase and use of Thermofight for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:
  - Cal. Civ. Code § 1770(a)(5), representing that goods have characteristics, uses, or benefits which they do not have;
  - Cal. Civ. Code § 1770(a)(7), representing that goods are of a particular standard, quality, or grade if they are of another;
  - Cal. Civ. Code § 1770(a)(9), advertising goods with intent not to sell them as advertised;
  - Cal. Civ. Code § 1770(a)(16), representing the subject of a transaction has been supplied in accordance with a previous representation when it has not; and
  - Cal. Civ. Code § 1770(a)(19), inserting an unconscionable provision in a contract.
- 310. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendants were unjustly enriched.
- 311. As a further result, Plaintiff and the Class have suffered damages, and because the conduct was deliberate, immoral, oppressive, made with malice and contrary to public policy, they are entitled to punitive or exemplary damages.
- 312. Plaintiff seeks an order enjoining Defendants' deceptive and unlawful advertising practices described herein and an order enjoining Defendants from entering into contracts which contravene

#### Case 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 62 of 113

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1	funda	mental public policies and/or violate Cal. Civ. Code § 1770(a)(19).
2		313. Pursuant to section 1782 et seq. of the CLRA, Plaintiff notified Defendants in writing by
3	certif	ied mail of the particular violations of § 1770 of the Act as to Thermofight and demanded that
4	Defer	ndants rectify the problems associated with the actions detailed above and give notice to all affected
5	consu	imers of its intent to so act.
6		314. Defendants received Plaintiff's written notice on April 19, 2021.
7		XXIII. PRAYER FOR RELIEF
8		315. WHEREFORE, Plaintiff, on behalf of herself, all others similarly situated, and the general
9	public	c, prays for judgment against Defendants as follows:
10	a.	An order confirming that this class action is properly maintainable as a class action as defined
11		above, appointing Plaintiff Aileen Brooks and her undersigned counsel to represent the Class, and
12		requiring Defendants to bear the cost of class notice;
13	b.	An order requiring Defendants pay \$500 in restitution, damages, and interest to Plaintiff;
14	c.	An order requiring Defendants pay \$5 million or a greater amount to be proven at trial in restitution
15		to Class members, and \$2000 to Plaintiff as an incentive award, or such greater amount the Court
16		deems fair and reasonable;
17	d.	An order requiring Defendants to disgorge any benefits received from Plaintiff and its unjust
18		enrichment realized as a result of its improper and misleading advertising, marketing, sale, and
19		distribution of the Weight Control Drugs;
20	e.	An Order declaring the conduct complained of herein violates the Unfair Competition Law;
21	f.	An order requiring Defendants to cease and desist their deceptive, unconscionable, and fraudulent
22		practices;
23	g.	An order requiring Defendants to engage in a corrective advertising campaign;
24	h.	An order declaring Defendants' "Terms of Use" to be void;
25	i.	An order enjoining Defendants from entering into contracts which violate California law;
26	i.	An award of prejudgment and post judgment interest;

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and reasonable; and

k. An award of attorney fees and costs of \$500,000, or such greater amount the Court awards as fair

#### Case 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 63 of 113 1. Such other and further relief as this Court may deem just, equitable or proper. XXIV. MAGISTRATE CONSENT / NO JURY DEMAND Plaintiff consents to a bench trial on all issues, and further consents to the jurisdiction of a United States magistrate judge. DATED: November 8, 2021 Respectfully Submitted, /s/ Gregory S. Weston THE WESTON FIRM **GREGORY S. WESTON** 1405 Morena Blvd., Suite 201 San Diego, CA 92110 Telephone: (619) 798-2006 Facsimile: (619) 343-2789 **Counsel for Plaintiff**

# EXHIBIT 1

#### Case 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 65 of 113



UNITED STATES OF AMERICA Federal Trade Commission WASHINGTON, D.C. 20580

April 24, 2020 Via Electronic Mail

It Works Marketing, Inc. c/o Timothy M. Seat, General Counsel 908 Riverside Drive Palmetto, Florida 34221

### Warning Regarding Earnings Claims Related to Coronavirus Disease 2019 (COVID-19)

Dear Mr. Seat,

FTC staff has reviewed social media posts made by It Works Marketing, Inc. ("It Works!"), on your social media website at https://www.facebook.com/TheOfficialItWorks/, and by It Works! business opportunity participants or representatives that unlawfully misrepresent that consumers who become It Works! business opportunity participants are likely to earn substantial income. This letter is to provide you with information about laws and regulations enforced by the Federal Trade Commission ("FTC") that may bear upon your business activities, including the activities of your business opportunity participants and representatives.

Some examples of earnings claims made on your corporate social media website include:

- A video with the description "... Because of It Works!, her family's income isn't impacted by COVID-19. Learn how you can start working from home and earning \$500 a month!," and the statement: "[E]veryone's getting stimulus checks right now.... There is no better investment you could do.... Take that money that you're about to get back... figure out a way to make this happen tonight."
- A video with the description "Tune in LIVE to learn how to build a business and earn an extra \$500 a month—all from the comfort of your couch!...," and the statements: "She joined this business...and decided to go for it and so January, February, March... she decided to go for it and ... earned herself that \$15,000 bonus.... That's life change right there, and it's possible.... In my organization in the business, we had 70 promotions in March... March 2020—a month that people... had a lot of uncertainty. We had people promote and move up in the ranks." A second person responds, "You guys, that could be you. If you're watching right now, that could be you.... There's a whole gamut of options for you guys, but there's also, like, the sky is the limit.... Can you imagine if you can take your family on dream vacations?... People are doing it. Why not you?"

Some examples of earnings claims made by your business opportunity participants or representatives include:

- "During the recession in 2008, my company went debt free. Right now during these hard times, my company is KILLING it. Why? Because people want to work from home. People see why this is such an amazing plan B.... Within 6 months I was making more than I was making at my government job! At the age of 29, I will become a millionaire all from my social media! At 23 I have been a top enroller top leader At 25 I will be a top income earner! And within all these years, I have paid every bill with this business, every trip/ vacation has been paid in cash ALL WHILE GIVING BACK!!.... So if you are struggling and need MORE, this is your chance."
- "So much uncertainty in the world right now but our team is NOT struggling. We are having the biggest month EVER and it's only the 4th! sooooo many people changing their LIFE right now and are pushing to earn a \$15,000 and \$20,000 bonuses! Working from home has never been such a blessing. Does anyone else need an income working from home right now?!"
- "I was going to ask who wants to earn \$500 from their phone but skrew that! Who wants to learn how to make a \$15,000 bonus!?! #gobig #andstayhome In such an unsure time I've been able to already help 2 girls on my team promote and double promote! Right now I'm charting 3 of them for their own \$15,000 bonuses!... And I can help you do the same if you're hard working and serious about this!... Ya girls about to hit a \$20,000 bonus When are you going to stop watching and wondering if this is real?"

Representations about a business opportunity, including earnings claims, violate Section 5 of the FTC Act, 15 U.S.C. § 41 *et seq.*, if they are false, misleading, or unsubstantiated and material to consumers. Express and implied earnings claims must be truthful and non-misleading to avoid being deceptive, which means that claims about the potential to achieve a wealthy lifestyle, career-level income, or significant income are false or misleading if business opportunity participants generally do not achieve such results. Even truthful testimonials from or about participants who do earn significant income or more will likely be misleading unless the advertising also makes clear the amount earned or lost by most participants. It Works! and your business opportunity participants and representatives must immediately cease making all express and implied earnings claims that would be false or misleading to current or prospective participants.

You are responsible for the claims of your business opportunity participants and representatives. As the FTC stated in the January 2019 <u>Business Guidance Concerning Multi-Level Marketing</u>, the compensation structure of a Multi-Level Marketing entity ("MLM") may create incentives for its participants to make certain representations to current or prospective participants. "As a consequence, an MLM should (i) direct its participants not to make false, misleading, or unsubstantiated representations and (ii) monitor its participants so they don't make false, misleading, or unsubstantiated representations."

#### Case 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 67 of 113

You are advised to review all claims relating to your business opportunity and immediately cease, and require your business opportunity participants and representatives to cease, making claims that are not supported by the evidence or substantiation described above.

Within 48 hours, please send reply via email to COVID-19-Task-Force@ftc.gov describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact us at COVID-19-Task-Force@ftc.gov.

Sincerely,

Federal Trade Commission Staff

# EXHIBIT 2

### THERMOFIGHT XX

NEXT GEN FAT BURN 2.0 †

60 Caplets

Ready for an easy change with extraordinary impact? ThermoFight  $X^{X}$  is designed to boost your metabolism and melt away fat. Our best-selling formula contains Caffeine and Jalapeño Pepper to help you achieve and maintain an ideal fat-burning mode.†

#### Features and Benefits:

- · Uses a clinically proven weight-loss ingredient that helps you lose an average of 31 pounds in 90 days!\*†
- Activates enhanced thermogenesis and boosts your energy<sup>†</sup>
- Accelerates ketosis by supporting rapid ketone generation<sup>†</sup>
- · Packs powerful ingredients like Green Coffee Bean, Chromium, Jalapeño Pepper, and Caffeine













SKU 30204

#### Supplement Facts

Serving Size: 1 Caplet Servings Per Container: 60

Amount F	Per Serving	%DV	
Calcium	140 mg	11%	
Chromium (as chromium dinicotinate glycinate)	200 mcg	571%	
Proprietary Green Tea Blend Greenselect® Phytosome green tea leaf/sunflower phospholipid complex and green tea leaf extract [provides min. 112.5 mg epigallocatechin-3-O-gallate (EGCG) and 62.5 mg caffeine]	437.5 mg	*	
Green coffee bean extract (Coffea robusta (provides min. 45 mg chlorogenic acids)	a) 100 mg	*	
Proprietary Thermogenic Blend Jalapeño pepper (fruit), Black pepper (fruit), ginger (root), cinnamon (bark), cayenne pepper (fruit).	75 mg	*	

#### SUGGESTED USE

Adults take one caplet two times daily with meals. Drink at least eight glasses of water daily.

Warning: Not recommended for those sensitive to caffeine. Keep out of reach of children. Consult your physician if you are pregnant, nursing, taking medications, or have a medical condition. Protect from heat, light, and moisture. Do not use if seal is broken or missing. Do not exceed the recommended daily dose. Do not take on an empty stomach. Should be taken with a meal. Store at 15-30°C (59-86°F).

Food supplements are not a substitute for a varied and balanced diet and a healthy lifestyle.

Ingredients: Calcium carbonate microcrystalline cellulose, stearic acid, croscarmellose sodium, hypromellose, silicon dioxide, magnesium stearate spirulina (color) glycerin, hydroxypropyl cellulose.



\*Daily value (DV) not established.

\*Greenselect\* Phytosome delivered an average weight loss of 31 pounds over 90 days when combined with a reduced-calorie diet, compared to an average of 11 pounds lost in the reduced-calorie diet control group. Weight-loss regime should include both exercise and a reduced-calorie diet. Greenselect\* is a registered trademark of Indena S.p.A., Italy.

### THERMOFIGHT XX

NEXT GEN FAT BURN 2.0 †

#### FREQUENTLY ASKED QUESTIONS

#### Why should I take ThermoFight X<sup>x</sup>?

By taking just two caplets each day, ThermoFight X<sup>x</sup> provides a simple, convenient way to help you lose weight through fat-burning thermogenesis! This premium formula includes powerful Green Tea extracts—including Greenselect® Phytosome—with clinically proven weightloss results that average 31 pounds over 90 days, \*† plus it contains Caffeine and Jalapeño Pepper to help you achieve and maintain your weight-loss goals.

#### What are the active ingredients in ThermoFight X<sup>x</sup>?

ThermoFight X<sup>x</sup> contains cutting-edge ingredients to support thermogenesis and weight management, such as:

- Green Tea, including Greenselect® Phytosome A thermogenic catalyst that burns stored fat†
- Green Coffee Bean An antioxidant superfood with chlorogenic acid to help you reach ketosis†
- Caffeine An energy driver that helps release fatty acids and boost your metabolic rate<sup>†</sup>
- Chromium A blood glucose balancer that helps keep sugar cravings under control<sup>†</sup>
- Jalapeño Pepper A thermogenic activator that helps break down stored fats for a metabolic burn<sup>†</sup>
- EGCG A thermogenic catalyst that accelerates fat burning<sup>†</sup>

#### What is thermogenesis?

Thermogenesis is the natural metabolic process your body uses to burn stored calories, a.k.a. fat! During this process, specialized fat cells convert the stored fat around your body and release it as heat. By powering up your thermogenic rate, you can boost your fat metabolism (or calorie burn) to aid weight loss by burning more stored energy!

#### Does ThermoFight X<sup>x</sup> contain gluten?

ThermoFight X<sup>x</sup> is formulated with only gluten-free ingredients. It is not currently tested for gluten that may or may not be introduced during the manufacturing process.

#### Can I give ThermoFight XX to my children?

ThermoFight  $X^{x}$  is recommended only for adults age 18 and older.

## Can I use ThermoFight X<sup>x</sup> if I am pregnant, nursing, taking medications or have ongoing medical conditions?

Before using any new product, we suggest that you consult your physician to find out if it is right for you. Not recommended for those sensitive to caffeine.



# EXHIBIT 3

CATEGORIES

PHONE APPS

BROWSER EXTENSIONS

FAQS

HOW IT WORKS

BLOG

SELLER TOOLS

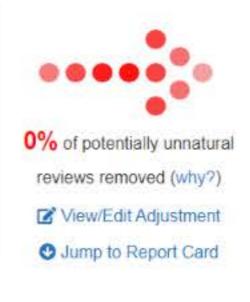
## Thermofight XX Next Gen Fat Burn 2.0- Even More Fat Burning Properties More product info Z

From It works!



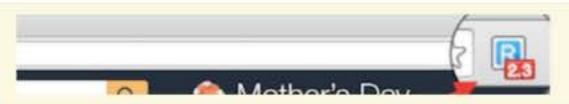




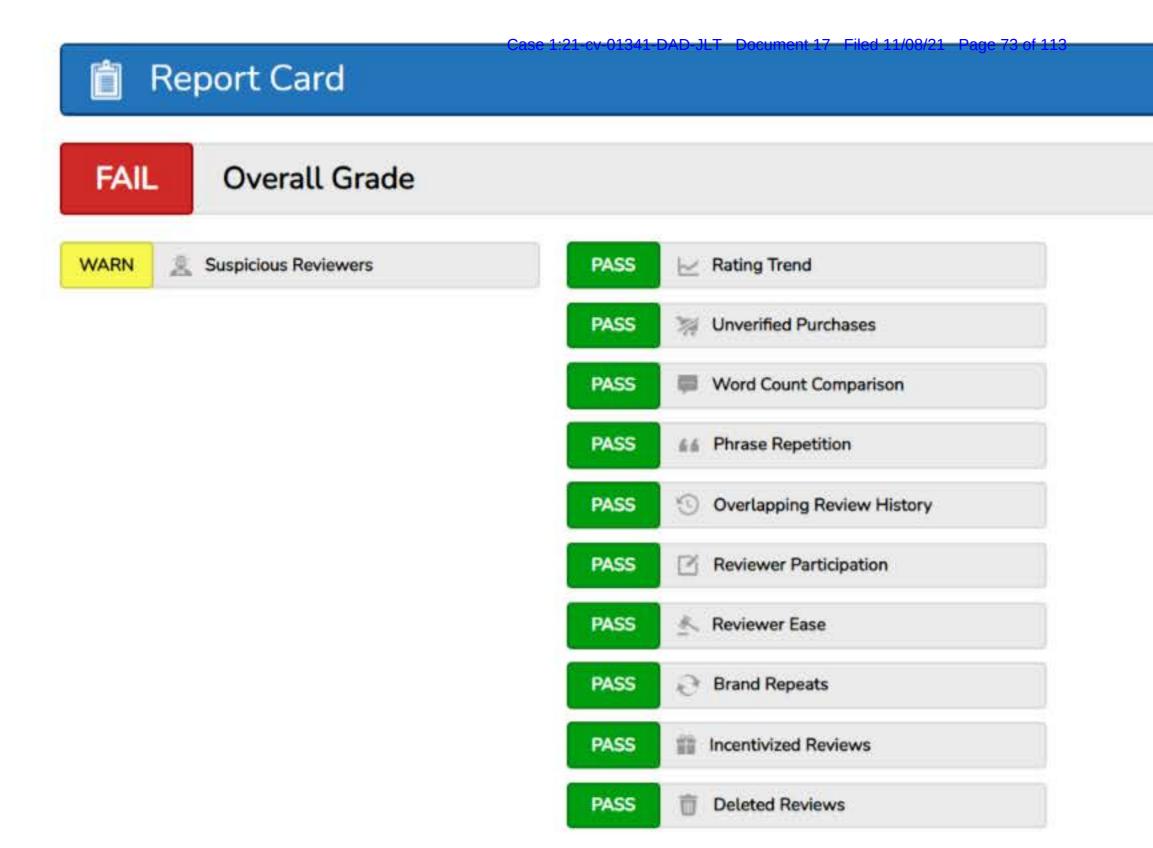














WARN

Suspicious Reviewers

## Take-Back Reviewers



27%

Have Previously Deleted Reviews

4 of the 15 reviewers have had at least one of their past reviews for another product deleted. While this is more Take-Back Reviewers than we'd expect to see, the discrepancy in ratings between the Take-Back Reviewers and reviewers who don't have any deleted reviews in their history isn't significant enough to rule out the possibility of it being due to random chance.



Read more about our Suspicious Reviewers test.

## **EXHIBIT 4**

### SLIMMING GUMMIES

#### WITH BLOOD ORANGE AND APPLE CIDER VINEGAR

60 Gummies

Shrink your waist and slim your hips with Slimming Gummies!† Enjoy these low-effort, high-reward gummies that guard against unwanted love handles and expanded waistlines.† With just a few Slimming Gummies each day, you can start losing stubborn, pinchable fat on your stomach and hips.† Formulated with Apple Cider Vinegar and a clinically proven Blood Orange power-ingredient, these sweet, vegan treats will keep your confidence up while you slim down.†\*

#### Features and Benefits:

- Features MOROSIL® Blood Orange extract, clinically proven to shrink waist and hip circumference by inches even lowering Body Mass Index!†\*
- $\cdot$  Attacks fattening calories that add unwanted inches to your stomach and hips  $^{\dagger}$
- Actively shrinks bloated fat cells so you can enjoy a slimmer body<sup>†</sup>
- Offers a uniquely vegan formula that's fruity, delicious, and contains no caffeine, stimulants, or added sugars







SUGGESTED USE



Adults enjoy two gummies at the same time

every day with or without food. For maximum,

clinically studied results, take two gummies twice daily.†\*Increased daily intake results in a total of 15





## **Supplement Facts**

Serving Size: 2 Gummies (6 g) Servings Per Container: 30

Amount Per	%DV		
Calories	10		
Total Carbohydrate	4 g	1%*	
Dietary Fiber	3 g	11%*	
Total Sugars	1 g	**	
Includes 0 g Added Sugars		0%*	
Apple cider vinegar	500 mg	**	
MOROSIL® Sicilian blood orange fruit extract	200 mg	**	
*The Derecht Deily \/elyes (D\/) are besed on			

\*The Percent Daily Values (DV) are based on a 2,000 calorie diet. \*\*Daily value (DV) not your physician if you are pregnant, nursing, taking medications, or have a medical condition. Protect from heat, light, and moisture. Store at 15-30°C (59-86°F). Do not use if tamper-evident seal is

Warning: Keep out of reach of children. Consult

broken or missing.

servings per bottle.

Other Ingredients: Sc-FOS, chicory root (inulin), water, pectin, citric acid, trisodium citrate, coconut oil, paprika, natural citrus flavors, and carnauba wax.



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#### **PRODUCT INFO**

### SLIMMING GUMMIES

#### WITH BLOOD ORANGE AND APPLE CIDER VINEGAR

#### FREQUENTLY ASKED QUESTIONS

#### When and how should I use Slimming Gummies?

Treat yourself to two delicious gummies every day, any time of day—the key to results is to take Slimming Gummies consistently for at least 90 days. For maximum, clinically studied results, double up and take two gummies twice a day—we recommend two in the morning and two in the afternoon!†\* (Please note that an increased daily intake will result in a total of 15 servings per bottle.)

With their fun, fruity flavor, Slimming Gummies are easy to enjoy, but remember: They are a powerful weight-control product, so don't eat more than four gummies a day.†

#### Why should I use Slimming Gummies?

Ever feel like everything you eat goes straight to your waist or hips? You need Slimming Gummies! These low-effort, high-reward gummies help you slim down by targeting existing fat in your midsection—particularly the pinchable fat that forms on stomachs and love handles.† They also minimize new fat accumulation in the same areas, so you can slow down weight gain from the start.† Slimming Gummies are an easy, great-tasting way to lose inches and keep them off†\*—plus, each vegan gummy is caffeine-free, stimulant-free, has 1 g net carbs, and no added sugars. Their unique formula features MOROSIL®, a clinically proven Blood Orange power-ingredient that helps shrink your waist, slim your hips, and even lower your BMI over time.†\*

## What are some of the key, active ingredients in Slimming Gummies?

- MOROSIL® Sicilian Blood Orange fruit extract –
   Obtained from the exotic juice of Moro Blood
   Oranges and loaded with naturally occurring fat
   inhibitors, MOROSIL is clinically proven to shrink
   waist and hip circumference by inches!†\*
- Apple Cider Vinegar Includes naturally occurring compounds that help reduce bloat, deter overeating, and support digestive health<sup>†</sup>
- Chicory Root Inulin A gut-friendly, soluble fiber and prebiotic that benefits digestive health<sup>†</sup>

#### How do Slimming Gummies work?

Slimming Gummies are uniquely formulated to target and attack fat from two directions—inhibiting lipogenesis while supporting lipolysis, which are metabolic processes your body must balance for weight management.<sup>†</sup>

- Slimming Gummies limit the build-up of new fat on your body—a process known as Lipogenesis.† As you consume extra calories, the active ingredients in Slimming Gummies help derail natural fat formation that can result in stubborn belly fat, bigger hips, and love handles.† Slimming Gummies offer a clinically proven, proactive first line of defense against the lipogenic accumulation of fat!†\*
- As for existing fat, Slimming Gummies also support Lipolysis—the breakdown and release of stored fat.<sup>†</sup>
  These super-gummies enhance lipolysis by shrinking bloated fat cells and dissolving some of the fat that's already on your body.<sup>†</sup> Over time, this helps you slim down as you lose unwanted inches!<sup>†\*</sup>

#### Do Slimming Gummies contain gluten?

Slimming Gummies are formulated with only glutenfree ingredients. They are not currently tested for gluten that may or may not be introduced during the manufacturing process.

#### Can I give Slimming Gummies to my children?

Slimming Gummies are recommended only for adults age 18 and older.

Can I take Slimming Gummies if I am pregnant, nursing, taking medication, or have a medical condition?

Before using any new product, we suggest that you consult your physician to find out if it is right for you.



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## EXHIBIT 5

#### PRODUCT INFO

## IT WORKS! CARB CONTROL DUAL-ACTION COMPLEX

60 Caplets

Pair your meals with peace of mind with It Works! Carb Control. Featuring results-driven ingredients, It Works! Carb Control helps control the impact of carbs on your body to reduce the accumulation of unwanted fat. †\* It works immediately with first use, so you can worry less about hidden sugars and starches in your food and cut yourself some slack. It also does double-duty by helping maintain blood-sugar balance, keeping your blood-glucose levels healthy. †\* Enjoy an indulgence and leave your carb concerns behind with It Works! Carb Control.

#### Features and Benefits:

- · Slows and controls your body's sugar and starch digestion—from the first use†
- · Minimizes the onset of carb-induced body fat and weight gain<sup>†\*</sup>
- Replaces carb-induced spikes and crashes with slower, balanced glucose absorption and level energy<sup>†</sup>
- Features marine-sourced, organically certified InSea2®, clinically proven to control your body's response to carbs†
- · Perfect for Keto enthusiasts and anyone keeping an eye on carb intake





Supplement Facts









#### Serving Size: 1 Caplet Servings Per Container: 60 Amount Per Serving %DV 2% Calcium Chromium (as Chromium 286% 100 mcg nicotinate glycinate chelate) Dual-Action Carb Blocking Blend: Organic InSea2® brown seaweed extract (20% polyphenols) from Ascophyllum nodosum and Fucus vesiculosus (providing less than 37.5 mcg iodine) and White kidney bean (Phaseolus vulgaris) extract.

Other Ingredients: Microcrystalline cellulose, dicalcium phosphate dihydrate, croscarmellose sodium, silicon dioxide, magnesium stearate (vegetable), hydroxypropyl methylcellulose, glycerin

#### **SUGGESTED USE**

Help your body block sugars and starches<sup>†</sup> by taking one caplet 30 minutes before moderate carb meals or two caplets before heavier carb consumption. Do not exceed two caplets per day. Drink at least 8 glasses of water daily.

#### CAUTION

Do not use if allergic to iodine. Consult your physician if you are pregnant, nursing, taking medication, or have a medical condition

#### WARNING

Keep out of reach of children. Protect from heat, light, and moisture. Store at 15-30°C (59-86°F). Do not use if tamper-evident seal is broken or missing.



Cinnamon bark (Cinnamomum

\*Daily Value (DV) not established.

cassia) 10:1 extract

\*Use as part of a healthy diet to help maintain healthy blood-sugar levels that are already within the normal range.

Product may also assist with weight control when used in conjunction with a sensible diet and exercise program.

InSea2® is a registered trademark of InnoVactiv Inc.

70 mg

US pis-carb-control-us-001w

#### **PRODUCT INFO**

## IT WORKS! CARB CONTROL DUAL-ACTION COMPLEX

#### FREQUENTLY ASKED QUESTIONS

#### How and when should I use It Works! Carb Control?

It Works! Carb Control helps catch hidden carbs in your food and drinks before they're absorbed into your body. There's no waiting period—it works immediately, every time. It's best to incorporate It Works! Carb Control into your daily routine, so keep it handy around mealtimes. Take one caplet about 30 minutes before a meal or snack with moderate carbs (sugars or starches). If your meal is expected to be carb-heavy, take two caplets, but do not exceed two per day.

It Works! Carb Control must be taken prior to eating to catch carbs before they hit your bloodstream.† It isn't effective if taken directly with food or after eating.

### What are some of the key, active ingredients in It Works! Carb Control?

Some of the active ingredients include:

- InSea2® Harvested by hand and organically certified from wild, brown seaweed, it's clinically proven to slow carb-to-glucose conversion†
- Cinnamon bark extract Activates cellular support of healthy blood-glucose levels†
- White kidney bean extract Alpha-amylase enzyme inhibitors that help block the breakdown of carbs to sugars, delaying carb absorption<sup>†</sup>
- Chromium An essential trace mineral that helps maintain healthy blood-sugar levels\* and reduce glycemic stress†

## What are carbs and how can It Works! Carb Control help me?

Carbohydrates are everywhere—not just in your pasta. They're hidden in everyday foods and drinks, and they give you cravings. Have you ever eaten a bag of chips, felt temporarily satisfied, yet found yourself hungry, agitated, and low on energy again just a few hours later?

That's a glycemic stress cycle fueled by carbs. Carbs spike your blood sugar, forcing your body to overreact with an insulin surge that tries to push circulating glucose into cells. That excess glucose must go somewhere, and in many cases, it ultimately converts to body fat and weight gain.

It Works! Carb Control works to minimize glycemic stress.† Each powerful caplet, with clinically proven InSea2®, slows carb digestion and absorption in your body to lessen blood-sugar spikes.†\* You'll experience more, balanced energy and less carb-induced body fat as a result.†\*

#### How should I eat while using It Works! Carb Control?

You'll experience optimal results by combining It Works! Carb Control with a healthy diet that's not regularly heavy with carbs. This product optimizes a healthy diet in which some carbs can still slip through. It also helps with an occasional indulgence!

#### Does It Works! Carb Control contain gluten?

It Works! Carb Control is formulated with only gluten-free ingredients. It is not currently tested for gluten that may or may not be introduced during the manufacturing process.

#### Can I give It Works! Carb Control to my children?

It Works! Carb Control is recommended only for adults ages 18 years and older.

## Can I use It Works! Carb Control if I am pregnant, nursing, or have ongoing medical conditions?

If you are pregnant, nursing, or have an ongoing medical condition, we suggest that you consult your physician to find out if It Works! Carb Control is right for you.



## EXHIBIT 6

#### PRODUCT INFO

### ADVANCED FORMULA FAT FIGHTER™

#### WITH CARB INHIBITORS<sup>†</sup>

60 Tablets

Find forgiveness from your next pizza night with Advanced Formula Fat Fighter! Powered by NeOpuntia® from the prickly pear cactus, Advanced Formula Fat Fighter absorbs some of the fat and carbohydrates from your food so your body doesn't!† Keep it with you all the time and take it up to one hour after your biggest meal of the day, a trip to the drive-thru, or a carb-heavy snack.

#### Features and Benefits:

- · Blocks some of the fat and carbs from everyday foods and drinks†
- Helps balance healthy blood-glucose levels and reduce cravings<sup>†</sup>
- Features a cactus-based formula with White Kidney Bean Extract
- Designed to be taken up to an hour after eating











#### Supplement Facts

Serving Size: 2 Tablets Servings Per Container: 30

Amount Per Serving			
Calcium	135 mg	10%	
Chromium (as chromium nicotinate)	150 mcg	429%	
NeOpuntia® Prickly pear cactus leaf	500 mg	*	
Plant-Based Metabolism Blend: 442 mg Garcinia fruit rind extract (50% hydroxycitric acid), white kidney bean extract, green tea leaf extract (50% caffeine) (providing 22 mg caffeine), banaba (Lagerstroemia speciosa) leaf extract (1% corosolic acid), gymnema leaf, bitter melon fruit, protein isolate (wheat), vanadium (as vanadyl sulfate)			

#### SUGGESTED USE

Adults take two tablets within 60 minutes of eating your main meal of the day. Allow one to two hours between use of this product and other supplements or medications. Drink at least eight glasses of water daily.

Warning: Keep out of reach of children. Consult your physician if you are pregnant, nursing, taking medications, or have a medical condition. Protect from heat, light, and moisture. Store at 15 - 30°C (59 - 86°F). Do not use if tamper-evident seal is broken or missing.

Other Ingredients: Dicalcium phosphate dihydrate, microcrystalline cellulose, stearic acid, croscarmellose sodium, silica, magnesium stearate (vegetable), coating (hypromellose and glycerin)



\*Daily Value (DV) not established.

#### PRODUCT INFO

### ADVANCED FORMULA FAT FIGHTER™

#### WITH CARB INHIBITORS<sup>†</sup>

#### FREQUENTLY ASKED QUESTIONS

#### How and when should I use Advanced Formula Fat Fighter?

Use Advanced Formula Fat Fighter when you need a little extra help after an occasional indulgence. Simply take two tablets within 60 minutes of eating your largest meal of the day to stay guilt-free! Allow one to two hours between the use of this product and other supplements or medications. Be sure to drink at least eight glasses of water daily.

#### Why should I use Advanced Formula Fat Fighter?

Everyone has moments of regret after an occasional fattening indulgence, but you don't have to feel guilty with Advanced Formula Fat Fighter. Take it as soon as 15 minutes after eating, and let it go to work right away—targeting fat and carbs from the food you just consumed.† Its powerful formula uses active ingredient NeOpuntia®—derived from the prickly pear cactus—as a vegetarian, fat-fighting ingredient that provides you with peace of mind.

#### What is the key, active ingredient in Advanced Formula Fat Fighter?

Suppress the effects of carbs and fats with these powerful, plant-based ingredients:†

- NeOpuntia® A powerful, naturally based ingredient from the prickly pear cactus that binds to the fats from foods in your stomach to help keep them from being absorbed by your body†
- White Kidney Bean Extract Acts as a carb inhibitor to help temper your body's starch-to-sugar digestive process†

#### How does Advanced Formula Fat Fighter work?

One of the active ingredients in Advanced Formula Fat Fighter is NeOpuntia®, derived from the prickly pear cactus. It's a vegetarian ingredient with natural fibers that have lipopholic properties, meaning they bind to fat from the foods in your stomach.† As a result, some of the fat is excreted from your system naturally instead of being absorbed by your body.† It also contains White Kidney Bean Extract, which acts as a carb inhibitor. White Kidney Bean Extract paralyzes the enzyme in your small intestine that turns starch from carbs into sugar during the digestive process.† This prevents the body from absorbing some of those carbohydrates, and they are also excreted naturally.†

#### Can I take Advanced Formula Fat Fighter every day?

Yes, Advanced Formula Fat Fighter is a plant-based product that is formulated for daily use. Because Advanced Formula Fat Fighter works in the stomach to absorb fat and in the small intestine to block carbs from foods you've already eaten, we recommend you take one to two tablets between 15 minutes to one hour after eating your largest meal of the day, or after eating snacks with high fat-content.†

### Can I take Advanced Formula Fat Fighter with other supplements or medications?

Because of its binding properties, Advanced Formula Fat Fighter should not be taken at the same time as other supplements or medications. Allow one to two hours to pass between taking Advanced Formula Fat Fighter and using other supplements or medications.

#### Does Advanced Formula Fat Fighter contain gluten?

Advanced Formula Fat Fighter is created with only gluten-free ingredients. It is not currently tested to detect gluten that may or may not be introduced during the manufacturing process.

### Can I use Advanced Formula Fat Fighter if I am pregnant, nursing, taking medications, or have a medical condition?

Before using any new product, we suggest that you consult your physician to find out if it is right for you.

#### Can I give Advanced Formula Fat Fighter to my children?

Advanced Formula Fat Fighter is recommended only for adults ages 18 and older.



## EXHIBIT 7

#### **WARNING LETTER**

#### **Genesis Nutrition Ultra Slim dba Genesis Ultra Slim**

MARCS-CMS 616040 - AUGUST 06, 2021

livery	

VIA Electronic Mail

**Product:** 

Drugs

#### **Recipient:**

Maria Gonzalez

Public Relations Contractor

Genesis Nutrition Ultra Slim dba Genesis Ultra Slim

10108 NW 77th Street

Doral, FL 33178

**United States** 

- <u> info@genesisultraslim.com (mailto:info@genesisultraslim.com)</u>
- <u>mgonzalez@genesisultraslim.com (mailto:mgonzalez@genesisultraslim.com)</u>
- ketoultraslimplus@gmail.com (mailto:ketoultraslimplus@gmail.com)

#### **Issuing Office:**

Office of Pharmaceutical Quality Operations, Division II **United States** 

August 6, 2021

Case #: 616040

#### **WARNING LETTER**

#### Ms. Gonzalez:

This letter is to advise you that the United States Food and Drug Administration (FDA) has reviewed your firm's websites at www.fastweightlossgarcinia.com and www.ketoultraslimplus.com between June and July 2021 and has determined that your firm takes orders there for "Genesis Ultra Gold." We have also reviewed your social media websites at www.facebook.com/genesisultraslim, https://twitter.com/genesis\_slim and www.instagram.com/genesis\_slim/; these

social media was ites direct consumers to your website www. rastweightides gard no 18 20m 1 to authors of our products.

The claims on your websites and social media websites establish that your "Genesis Ultra Slim Gold" product is intended for weight loss. Therefore, this product is an unapproved new drug sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d), and a misbranded drug sold in violation of sections 502 and 301(a) of the FD&C Act, 21 U.S.C. 502 and 331(a). You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov (http://www.fda.gov).

FDA confirmed through laboratory analysis that a sample of your "Genesis Ultra Slim Gold" contains undeclared sibutramine and phenolphthalein. Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and, subsequently, withdrawn from the United States market on December 21, 2010 after clinical data indicated sibutramine poses an increased risk of heart attack and stroke. Phenolphthalein is a chemical that is not an active ingredient in any approved drug in the United States. Studies have indicated that it presents a cancer-causing risk.

FDA has issued a warning to consumers not to use "Genesis Ultra Slim Gold" (see Genesis Ultra Slim Gold Immediate Public Notification).

#### **Unapproved New Drug**

You market "Genesis Ultra Slim Gold" as a dietary supplement. However, under section 201(ff)(3)(B)(ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(ii), a dietary supplement may not include an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or food before it was authorized for investigation as a new drug.

The investigational new drug (IND) application for Meridia (sibutramine) was received by FDA on December 24, 1985, and sibutramine became authorized for investigation as a new drug under an IND on January 23, 1986. When Meridia was approved for marketing as a new drug in the United States, the existence of substantial completed clinical investigations of sibutramine became public. Based on the information available to FDA, sibutramine was not marketed as a dietary supplement or as a food until after it was authorized for investigation as a new drug. Therefore, "Genesis Ultra Slim Gold," which contains sibutramine, is excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(ii) of the FD&C Act.

Your "Genesis Ultra Slim Gold," is an article (other than food) intended to affect the structure or function of the body and, thus, is a drug as defined by section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1). Some examples of claims observed on your websites and social media websites that establish the intended use of your product as a drug include, but may not limited to, the following:

On your websites www.fastweightlossgarcinia.com and www.ketoultraslimplus.com

- "Our natural blend of ingredients can benefit you by . . . [s]uppressing your appetite . . . [b]oosts your metabolism . .. [b]urn fat & calories ... [i]ncrease energy levels ... "
- "Complete blend of 100% natural ingredients formulated to help you lose weight . . ."

On your website www.fastweightlossgarcinia.com

- "Konjac root . . . slows the rate of digestion and the absorption of both fat and carbohydrates."
- "[P]ineapple is anti-inflammatory . . . "

• "Dry Greek Apold Powder 41 that detailifying problement of sure lifethed differed and it 87 so helps relieve constipation."

On your Facebook Account www.facebook.com/genesisultraslim

 January 22, 2020 posting - "Genesis UltraSlim Gold . . . Lose up to 20 pounds in just 4 weeks . . . Promotes weight loss"

On your Instaram Account www.instagram.com/genesis slim/

 May 7, 2021 posting - "Benefits . . . appetite suppression . . . reduce bloating . . . burns fat . . . reduce inches . . . potentiates weight loss . . . improves metabolism"

Your "Genesis Ultra Slim Gold" product is not generally recognized as safe and effective for its above referenced uses and, therefore it is a "new drug" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. There is no FDA-approved application in effect for your product.

#### Misbranded Drug

Your "Genesis Ultra Slim Gold" product is misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), in that the labeling for this drug fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. (See 21 CFR 201.5). It is impossible to write "adequate directions for use" for "Genesis Ultra Slim Gold" for at least two reasons: 1) prior to withdrawal of Meridia's approval, FDA approval of sibutramine was limited to use under the professional supervision of a practitioner licensed by law to administer such drugs and 2) FDA approval of Meridia was withdrawn because of serious safety risks. As such, the labeling of "Genesis Ultra Slim Gold" fails to bear adequate directions for its intended uses, causing it to be misbranded under section 502(f)(1) of the FD&C Act. Under 21 CFR 201.100(c)(2) and 201.115, FDAapproved prescription drugs that bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your "Genesis Ultra Slim Gold" product is not exempt from the requirement that its labeling bears adequate directions for use because no FDA-approved application is in effect for this product.

Additionally, under section 502(a) of the FD&C Act, 21 U.S.C. 352(a), a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act, 21 U.S.C. 321(n) provides that, in determining whether an article's labeling or advertising "is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations . . . ." Your "Genesis Ultra Slim Gold" product is misbranded under section 502(a) of the FD&C Act because the labeling fails to reveal its sibutramine and phenolphthalein content, which are material facts with respect to consequences that may result from the use of this product. As described above, sibutramine and phenolphthalein may pose health risks to consumers which are only compounded by the fact that neither ingredient is declared on the label.

"Genesis Ultra Slim Gold" is also misbranded under section 502(f)(2) of the FD&C Act, 21 U.S.C. 352(f)(2), because the product labeling lacks adequate warnings for the protection of users. As noted, there is potential for adverse events associated with the use of this product, particularly since someone who takes it would be unaware of the presence of the undeclared ingredients.

Likewise, "Genesis-Lifting SMIND 63101 is Philippinal and a procession 502(iFile He 1-1508/Adt, 2P 005-09 852/i) 1. 13 cause it is dangerous to health when used in the dosage or manner recommended in the labeling. As previously noted, sibutramine poses an increased risk of heart attack and stroke.

The introduction or delivery for introduction into interstate commerce of this misbranded drug product is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

#### Conclusion

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and/or injunction.

Your websites, www.fastweightlossgarcinia.com and www.ketoultraslimplus.com, also market the following products: Genesis Ultra Slim Original Formula, Genesis Ultra Slim Fat Burner, Genesis Ultra Slim Colon Cleanse, Garcinia Max, Genesis Ultra Slim Platinum, Keto Ultra Slim Plus, and Keto 15 Day Cleanse. While FDA has not tested these products marketed by your firm, you are responsible for ensuring that they do not contain undeclared ingredients.

A full list of all tainted products discovered by FDA can be found at http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted supplements cder.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective actions within fifteen working days, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Your written notification should refer to case # 616040 .

Please electronically submit your reply, on company letterhead, to Dayna I. Martinez, Compliance Officer, at ORAPHARM2 RESPONSES@fda.hhs.gov. In addition, please submit a signed copy of your response to dayna.martinez@fda.hhs.gov . and john.diehl@fda.hhs.gov .

If you have questions regarding the contents of this letter, you may contact Dayna I. Martinez via phone at 787-729-8608 or email at dayna.martinez@fda.hhs.gov.

Sincerely, /S/

John W. Diehl, M.S. Program Division Director (Acting)

Office of Pharmaceutical Quality Operations, Division II

1 Your Twitter and Facebook accounts unear Downgent 17 Utrasiling on 113 www.fastweightloss garcinia.com.

**♦** More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

#### **WARNING LETTER**

#### **TEK Naturals**

MARCS-CMS 565026 - FEBRUARY 05, 2019

#### **Product:**

**Dietary Supplements** 

#### Recipient:

Trevor Rose

CEO

**TEK Naturals** 

1985 Riviera Dr

103-127

Mount Pleasant, SC 29464

**United States** 

#### **Issuing Office:**

Center for Food Safety and Applied Nutrition 5001 Campus Drive College Park, MD 20740-3835 United States

UNITED STATES OF AMERICA DEPARTMENT OF HEALTH
FEDERAL TRADE COMMISSION AND HUMAN SERVICES
BUREAU OF CONSUMER PROTECTIONFOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20580 SILVER SPRING, MD 20993

#### WARNING LETTER

VIA OVERNIGHT DELIVERY RETURN RECEIPT REQUESTED

February 5, 2019

TEK Naturals
Trevor Rose, CEO
1985 Riviera Dr
103-127
Mount Pleasant, SC 29464

RE: 565026 ase 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 91 of 113

Dear Mr. Rose:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites at the Internet addresses www.burn4her.com, www.burnertek.com, www.mindignite.com, www.tekmale.com, www.tekmale.com, and www.teknaturals.com in September 2018 and has determined that you take orders there for your products BURN4Her, BurnerTEK, Mind Ignite, TEK Male, and TestoTEK. FDA also reviewed your social media websites at www.facebook.com/TEKNaturals and www.twitter.com/TeKNaturals, which contain links to your website at www.teknaturals.com, and www.instagram.com/teknaturals, which contains links to your website at www.burn4her.com. The claims on your websites establish that these products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1) (B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

Examples of some of the website claims that provide evidence that your products are intended for use as drugs include the following:

On the "BURN4HER INGREDIENTS" page of your www.burn4her.com website:

- •"BURN4HER's™ INGREDIENTS"
- o "Green Tea Extract ... Green Tea's polyphenols are scientifically proven to ... reduce a woman's risk for heart disease."
- o "Green Coffee Beans ... use of chlorogenic acid from green coffee bean extracts as an important inhibitor of diet-related obesity and obesity-related metabolic syndrome ... [and] promote significant weight loss in individuals who suffer from morbid obesity. The extract has also shown positive effects in the regulation of high blood pressure and as an anti-diabetic supplement."
- o "Glucomannan ... reduce feelings of anxiety"
- o "L-Carnitine ... is well-known for its anti-anxiety benefits."

On the "BURNERTEK INGREDIENTS" page of your www.burnertek.com website:

- "BurnerTEK includes scientifically-researched, consistent potencies of the following ... ingredients:"
- o "Green Tea Extract ... possesses a wide range of therapeutic properties that are used in the treatment and prevention of some forms of cancer, Parkinson's disease, human papilloma virus, and kidney stones."
- o "Green Coffee Beans ... The extract has also shown positive effects in the regulation of high blood pressure and as an anti-diabetic supplement."
- o "... Glucomannan is responsible for lowered LDL cholesterol"
- o "Cayenne Pepper ... has been the treatment of ear infections ... and even some forms of cancer..."
- o "[T]urmeric has a significant effect on obesity and insulin resistance.... Turmeric also helps combat the effects of obesity, notably inflammation..."
- o "L-Carnitine plays a vital role in the reduction of blood glucose levels.... It has also been shown to have a significant influence on the improvement of insulin sensitivity."
- o "Vitamin B-Complex ... provid[es] a slew of benefits and therapeutic effects including ... resistance to disease, reduction of inflammation, [and] the prevention of memory loss..."
- o "Chromium Picolinate ... [is] used as a dietary supplement in the treatment and management of Type 2

Diabetes....Coronican Picolinale supplied the body with its lessential supply of elementar chromium. Elemental chromium plays a direct role in the control of LDL cholesterol, triglycerides, and indirectly prevents several types of heart disease."

On the home page of your www.mindignite.com website:

- "Mind IgniteTM is a safe and highly effective alternative to Adderall. . . . Clinically shown to help diseases of the brain such as Alzheimer's and even dementia."
- •"Adderall and similar drugs used to treat ADD and ADHD, are among the most abused drugs in the U.S. and abroad.... [T]he drugs can be highly addictive.... Mind IgniteTM is a safe and highly effective alternative to Adderall."
- •"In fact, some of [Mind Ignite'sTM sixteen] ingredients have been clinically shown to help diseases of the brain such as Alzheimer's and even dementia."
- •"The ingredients in Mind Ignite ... are used to treat Alzheimer's."

On the "Mind IgniteTM Ingredients" page of your www.mindignite.com website:

- •"Mind IgniteTM Ingredients"
- o "...Bacopa Monnieri is a natural ... anti-anxiety aid."
- o "Alpha GPC ... is such a powerful nootropic ingredient that it is being tested as a possible treatment for Alzheimer's patients."
- o "Ginkgo Biloba is known to ... treat the symptoms of ADD and ADHD..."
- o "L-Tyrosine is an important amino acid that can ... reduce anxiety"
- o "The benefits of PS [Phosphatidylserine] ... counteract the symptoms of ADHD..."
- o "Huperzine A ... is also known to help treat Alzheimer's."
- o "St. John's Wort Extract ... eases ... anxiety. It also has been known to alleviate symptoms of ADHD.... The key compound in the herb is hypericin which is primarily responsible for helping with depression."
- o "Studies have shown that vitamins B-6 and B-12 specifically can help prevent cognitive decline and even help in preventing dementia and Alzheimer's."

On the "TEKMALE INGREDIENTS" page of your www.tekmale.com website:

#### •"TEKMALE INGREDIENTS"

- o "One particular clinical study of Korean Ginseng was done on a group of 45 impotent men. They supplemented with highly standardized Korean Ginseng for weeks and the study resulted in over 60% of the men no longer being impotent."
- o "Muira Puama ... has the ability to fight ... premature ejaculation..."
- o "Yohimbe Bark Extract is actually used in a large number of countries as a prescription drug for erectile dysfunction.... Yohimbe Bark Extract is as close as you can get to taking Viagra, it's that effective."

On the "TESTOTEK INGREDIENTS" page of your www.testotek.com website:

#### •"TESTOTEK INGREDIENTS"

- o "Vitamin B6 ... helps in the production of serotonin, a chemical that is vital to fighting off depression and anxiety."
- o "Vitamin B5 is essential because it helps regulate cholesterol..."
- o "Siberian ginseng ... has long been used to ... lower blood pressure, and help treat Alzheimer's and diabetes."

Additional Casamplies of Some 34th Casamplon your convertes have the hard of 11 wing:

On the blog page titled "The Bedroom Benefits of Ginkgo Biloba" (Ginkgo Biloba is an ingredient in your products Mind Ignite and TEK Male):

- •"[Ginkgo Biloba] has been used to act as a natural remedy for erectile dysfunction..."
- •"Benefits of Ginkgo Biloba"
- o "Reduces risk for neurodegenerative diseases"
- o "Fights anxiety and depression"
- o "Treats adhd [sic]"
- o "Treats migraines"

On the blog page titled "The Many Benefits of Ginseng" (Ginseng is an ingredient in your product TEK Male):

- "Benefits of Ginseng"
- o "Anti-inflammatory agent"
- o "Helps prevent cancer"
- o "Reduces likelihood of getting erectile dysfunction"
- •"... Ginseng could now be used as an alternative to Viagra."
- •"[Ginseng] has been used to treat people suffering from erectile dysfunction..."

On the blog page titled "New Mind Ignite Review from HealthToday.com," there is a link to a review of your Mind Ignite product on http://healthtoday.com/mind-ignite-review-top-nootropic-market/. Your post states, "Check out this all new detailed review of our ... Mind IgniteTM."

The linked article, which you endorsed, contains evidence of intended use in the form of a personal testimonial recommending or describing the use of Mind Ignite for the cure, mitigation, treatment, or prevention of disease. An example of such testimonials, which provide evidence that your product is intended for use as a drug, includes:

•"I became addicted, right at the point that Adderall lost its effect.... I came across brain supplements, better known as nootropics, while researching natural ADHD cures. I was hesitant at first, however, after trying a few well-reviewed ingredients, my mind began to change ... consumers [are] switching from Adderall to nootropics."

Your www.mindignite.com website also contains evidence of intended use in the form of personal testimonials. An example of such testimonials includes:

•"I take Mind Ignite every day. I have struggled with ADHD for many years and took Adderall but stopped because of the side effects. My friend recommended Mind Ignite and it works for me..."

Also, claims made on your Facebook page at https://www.facebook.com/TEKNaturals, which provides links to your website at www.teknaturals.com, provide additional evidence that your products are intended for use as drugs:

Posts by your company on your Facebook timeline page include the following:

- •On August 17,24i8:1"Mind Puland An-illgTedlent IN TER Male F. !! Glovides (2n) ... Effect M. Ofredting erectile dysfunction"
- •On November 29, 2017, your post states, "Read this detail review for more information" and links to a review on http://thesupplementreviews.org/nootropics/mind-ignite-review/. The linked review, which you endorsed, provides additional evidence that your products are intended for use as drugs:
- o "Mind Ignite Review"
- •"[T]hese supplements are designed to counter the symptoms of ADD and ADHD"
- •"Nootropics are generally all-natural and safe-alternatives to Adderall and other prescription ADD/ADHD drugs."
- •"Below we will outline these [Mind Ignite] ingredients so that you can get a feel for what each one's specific role is."
- •Ginkgo Biloba Extract ... will help to counteract the symptoms of ADD and ADHD"
- •"L-Tyrosine ... is a great natural alternative to the amphetamine that is found in drugs like Adderall."
- •"Vitamins ... B6 and B12 specifically can reverse mental decline from aging or people who suffer with dementia or even Alzheimer's."

Claims on your Twitter page at www.twitter.com/TeKNaturals, which provides links to your website at www.teknaturals.com, provide additional evidence that your products are intended for use as drugs:

Posts by your company on your Twitter page include the following:

- •On January 16, 2018, your post states, "Still getting great reviews for ... BurnerTEK and links to a review on www.iast.net/fat-burners/burnertek-review/. This linked review, which you endorsed, includes the following claim:"
- o "BurnerTEK Ingredients"
- "Green Coffee Bean Extract ... Chlorogenic acid, a primary ingredient found in green coffee bean extract, has been proven in various independent studies to counter the effects of diabetes."

Furthermore, claims made on your Instagram page at www.instagram.com/teknaturals, which provides links to your website at www.burn4her.com, provide additional evidence that your products are intended for use as drugs:

Posts by your company on your Instagram page include the following:

- •On September 24, 2017: "Ever heard of nootropics? These are powerful natural brain boosters that serve as alternatives to the prescription drug Adderall." [Your product Mind Ignite is described on its product page as a nootropic.
- •On July 9, 2017: "Here is a list of the major benefits men in our studies have reported experiencing since they started using TEKMale... ELIMINATE PREMATURE EJACULATIONS"

Your products BURN4Her, BurnerTEK, Mind Ignite, TEK Male, and TestoTEK are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

Your products BURN4Her, BurnerTEK, Mind Ignite, TEK Male, and TestoTEK are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, BURN4Her, BurnerTEK, Mind Ignite, TEK Male, and TestoTEK fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation.

If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your written reply should be directed to Shawn Goldman, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Drive, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Mr. Goldman at Shawn.Goldman@fda.hhs.gov.

Sincerely,
/S/
William A. Correll Jr.
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Case 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 96 of 113

Mary K. Engle

**Associate Director** 

**Division of Advertising Practices** 

Federal Trade Commission

• More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

#### **WARNING LETTER**

#### Je Dois Lavoir LLC

MARCS-CMS 616016 - AUGUST 11, 2021

Delivery Method:
Via Email
Product:
Drugs
Recipient:
Sandra Orozco
CEO CEO
Je Dois Lavoir LLC
(b)(6)
United States
<u> cs@jedoisavoir2020.com (mailto:cs@jedoisavoir2020.com)</u>
<u>sorozco30@icloud.com (mailto:sorozco30@icloud.com)</u>
Issuing Office:
Division of Pharmaceutical Quality Operations IV
United States

#### WARNING LETTER

August 11, 2021

Dear Ms. Orozco:

This letter is to advise you that the United States Food and Drug Administration has reviewed your website at https://jedoisavoir2020.com in June 2021 and has determined that you take orders there for "365 Skinny High Intensity." We have also reviewed your social media websites at www.facebook.com/jdl2020 and www.instagram.com/j\_d\_l2020; these social media websites direct consumers to your website https://jedoisavoir2020.com to purchase your products. The claims on your website and social media websites establish that your "365 Skinny High Intensity" product is intended for weight loss. Therefore, this product is an unapproved new drug sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d), and a misbranded drug sold in violation of sections

502 and 361(a) of the FD&ClAd, 12PO.S.cl. 502 and 351(a). You can find the PDA regalations through links on FDA's home page at <a href="https://www.fda.gov.(//www.fda.gov.">www.fda.gov/about-fda/website-policies/website-disclaimer</a>)

FDA confirmed through laboratory analysis that a sample of your "365 Skinny High Intensity" contains undeclared sibutramine. Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and, subsequently, withdrawn from the United States market on December 21, 2010 after clinical data indicated sibutramine poses an increased risk of heart attack and stroke.

FDA has issued a warning to consumers not to use "365 Skinny High Intensity" (see 365 Skinny High Intensity Immediate Public Notification).

#### **Unapproved New Drug**

You market "365 Skinny High Intensity" as a dietary supplement. However, under section 201(ff)(3)(B)(ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(ii), a dietary supplement may not include an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or food before it was authorized for investigation as a new drug.

The investigational new drug (IND) application for Meridia (sibutramine) was received by FDA on December 24, 1985, and sibutramine became authorized for investigation as a new drug under an IND on January 23, 1986. When Meridia was approved for marketing as a new drug in the United States, the existence of substantial completed clinical investigations of sibutramine became public. Based on the information available to FDA, sibutramine was not marketed as a dietary supplement or as a food until after it was authorized for investigation as a new drug. Therefore, "365 Skinny High Intensity," which contains sibutramine, is excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(ii) of the FD&C Act.

Your "365 Skinny High Intensity," is an article intended to diagnose, cure, mitigate, treat, or prevent disease and/or an article (other than food) intended to affect the structure or function of the body and, thus, is a drug as defined by section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1). Some examples of claims observed on your website and social media websites that establish the intended use of your product as a drug include, but may not limited to, the following:

On your website https://jedoisavoir2020.com

• "365 Skinny High Intensity new silver label Strong Formula 2020 are [sic] giving excellent results in the loss of weight with a single capsule a day!"

On your website https://jedoisavoir2020.com and Facebook Account, www.facebook.com/jdl2020, October 19, 2020 Post

- "It is a totally natural herbal supplement for anti obesity that controls anxiety, inhibits appetite, burns fat, high cholesterol, helps with sugar levels, accelerates metabolism, eliminates toxins, reduce swelling and increase your energy."
- "How does this capsule work? . . . Appetite Control . . . Accelerates metabolism . . . Increase your energy . . . Causes satiety . . . Burn fat through the urine . . . Eliminates toxins in the skin . . . Regenerates muscle mass . . . Reduces fat deposits and cellulite . . . Increases libido . . . Balances insulin and blood sugar levels"
- "Bitter orange extract: reduces 'bad' cholesterol prevents digestive disorders and regulates bowel movement"

[sic] Case 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 99 of 113

- "Cassia seed: combat constipation"
- "Alism: eliminates fluid retention, reduces appetite"

Your "365 Skinny High Intensity" product is not generally recognized as safe and effective for its above referenced uses and, therefore it is a "new drug" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. There is no FDA-approved application in effect for your product.

#### **Misbranded Drug**

Your "365 Skinny High Intensity" product is misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), in that the labeling for this drug fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. (See 21 CFR 201.5). It is impossible to write "adequate directions for use" for "365 Skinny High Intensity" for at least two reasons: 1) prior to withdrawal of Meridia's approval, FDA approval of sibutramine was limited to use under the professional supervision of a practitioner licensed by law to administer such drugs and 2) FDA approval of Meridia was withdrawn because of serious safety risks. As such, the labeling of "365 Skinny High Intensity" fails to bear adequate directions for its intended uses, causing it to be misbranded under section 502(f)(1) of the FD&C Act. Under 21 CFR 201.100(c)(2) and 201.115, FDA-approved prescription drugs that bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your "365 Skinny High Intensity" product is not exempt from the requirement that its labeling bears adequate directions for use because no FDA-approved application is in effect for this product.

Additionally, under section 502(a) of the FD&C Act, 21 U.S.C. 352(a), a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act, 21 U.S.C. 321(n) provides that, in determining whether an article's labeling or advertising "is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations . . . ." Your "365 Skinny High Intensity" product is misbranded under section 502(a) of the FD&C Act because the labeling fails to reveal the sibutramine content, which is a material fact with respect to consequences that may result from the use of this product. As described above, sibutramine may pose health risks to consumers which are only compounded by the fact that the ingredient is not declared on the label.

"365 Skinny High Intensity" is also misbranded under section 502(f)(2) of the FD&C Act, 21 U.S.C. 352(f)(2), because the product labeling lacks adequate warnings for the protection of users. As noted, there is potential for adverse events associated with the use of this product, particularly since someone who takes it would be unaware of the presence of the undeclared ingredients.

Likewise, "365 Skinny High Intensity" is misbranded under section 502(j) of the FD&C Act, 21 U.S.C. 352(j), because it is dangerous to health when used in the dosage or manner recommended in the labeling. As previously noted, sibutramine poses an increased risk of heart attack and stroke.

The introduction of left of the FD&C Act, 21 U.S.C. 331(a).

#### Conclusion

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and/or injunction.

We acknowledge that your firm voluntarily recalled 365 Skinny High Intensity and 365 Skinny Emergency Boutique products on August 2, 2021. You also market other products on your website https://jedoisavoir2020.com, including foods, dietary supplements, and topicals. While FDA has not tested these products marketed by your firm, you are responsible for ensuring that they do not contain undeclared ingredients.

A full list of all tainted products discovered by FDA can be found at <a href="http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted\_supplements\_cder">http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted\_supplements\_cder</a>. (<a href="http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted\_supplements\_cder">http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted\_supplements\_cder</a>).

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective actions within fifteen working days, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Your response should refer to unique identifier CMS 616016 and be sent electronically to ORAPHARM4\_Responses@fda.hhs.gov or mailed to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food and Drug Administration
19701 Fairchild Road
Irvine, CA 92612

If you have any questions regarding this letter, please contact Jamie Dion, Compliance Officer, at 303-236-3133 or by email at Jamie.Dion@fda.hhs.gov.

Sincerely,

/S/

Lance M. De Souza

Acting Director, Division of Pharmaceutical Quality Operations IV

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

## EXHIBIT 8



908 Riverside Dr. Palmetto, FL 34221

#### IT WORKS! LOYAL CUSTOMER AGREEMENT TERMS & CONDITIONS UNITED STATES

It Works Marketing, Inc. shall be referred to as "It Works!" or "the Company" thoughout this Agreement. Where a customer has elected to become an It Works! Loyal Customer, they agree to the following terms and conditions:

#### I. GENERAL TERMS

- 1. The It Works! Loyal Customer Agreement allows a customer to enjoy Loyal Customer pricing on all orders.
- 2. There are two ways to become a Loyal Customer. (1) You can make a three (3) consecutive month minimum commitment to a monthly autoshipment order; or (2) You can enroll by making a \$50 Membership Fee payment and placing a single order for product.
- 3. A Loyal Customer must be at least 18 years of age as our products are intended for use by adults only.
- 4. The autoshipment order or initial order under the \$50 Membership Fee option must consist of any It Works! products that contain Bonus Volume (BV). Autoshipment orders may be changed online by using the Customer ID and password or by calling Customer Support (see below) at least two (2) business days <u>prior</u> to the Loyal Customer's next autoshipment.
- 5. The Loyal Customer may order products in addition to their autoshipment order at any time and receive Loyal Customer pricing.
- 6. The Loyal Customer may cancel the autoship program at any time after the three (3) month commitment has been fulfilled. The Loyal Customer is still considered a member of the It Works! Loyal Customer Agreement and will receive Loyal Customer pricing on future orders, subject to paragraph 9, below. The autoshipment will continue to run every month until the Loyal Customer contacts It Works! to change or end their autoshipment. To end participation in the It Works! Loyal Customer Agreement after the three (3) month commitment has been fulfilled, Loyal Customer can cancel online by logging into their account at www.itworks.com or they can contact Customer Support at the numbers listed below.
- 7. Loyal Customers who cancel their autoshipment prior to completing the three (3) month minimum commitment will be charged a \$50 Membership Fee. Payment of this \$50 Membership Fee does complete the Loyal Customer Agreement.
- 8. If a Loyal Customer wishes to upgrade to a Distributor and has completed the Loyal Customer Agreement or the Loyal Customer has paid the \$50 Membership fee, then the Loyal Customer is free to enroll as a Distributor under whomever they choose. If a Loyal Customer wishes to upgrade to a Distributor and has NOT completed the Loyal Customer Agreement and they want the Membership Fee to be waived, the Loyal Customer must enroll under their enrolling Distributor.
- 9. The accounts of Loyal Customers who do not place an order for two (2) years (twenty-four (24) consecutive months) will be cancelled and purged from the It Works! system. Orders placed after the Loyal Customer has been removed from the system following two years of inactivity will require entering into a new It Works! Loyal Customer Agreement pursuant to paragraph 2, above.
- 10. It Works!, including but not limited to any of its affiliates and/or subsidiaries, may transfer or assign this Agreement in its sole discretion. In the case that the Loyal Customer does not accept the transfer or assignment, they may provide written notice that they wish to terminate this Agreement. In the event of such notice being provided, the termination will become effective immediately.

#### II. IT WORKS! PRODUCT REFUNDS AND RETURNS POLICY

 As It Works! products produce different results for different people, It Works! does not guarantee specific results nor offer a money back guarantee. Loyal Customers should follow the directions with each product received.

#### Case 1:21-cv-01341-DAD-JLT Document 17 Filed 11/08/21 Page 103 of 113



908 Riverside Dr. - Palmetto. FL 34221

- 2. The Loyal Customer can utilize the Self Service Returns process located in the Loyal Customer portal to generate a shipping label.
- 3. The Loyal Customer is responsible for all return shipping costs.
- 4. To receive a refund, all products must be post-marked within thirty (30) days of the ship date and all items must be in an unopened, "new" condition. When making a return, the Loyal Customer must use a traceable shipping method. It Works! is not liable for the shipping costs of returned products or any return shipments that may be lost in the return shipping process.
- 5. To receive a replacement product or a refund on incomplete or defective product, the Loyal Customer must report the matter within sixty (60) days from the date of delivery and the incomplete or defective product must be made available for inspection at the Returns Processing Center.
- 6. Refused orders are defined as orders that are refused upon delivery, marked return to sender, are undeliverable, or that have an insufficient address. A refused order is assigned a \$15 refusal fee that is deducted from the refund. Refusal fees are applied to orders to offset return shipping costs and return processing charges. Refused orders could take up to ninety (90) days to reach the Returns Processing Center and are not guaranteed a refund.
- 7. Loyal Customers that select the autoshipment membership option at enrollment must complete the Loyal Customer Agreement. If an order is returned at any time causing the total completed orders on the account to be less than three, It Works! will deduct a \$50 Membership Fee from the refund on the returned order. If the full amount of the Membership Fee cannot be deducted from the return, the Loyal Customer account will be canceled. Loyal Customers that select the \$50 Membership Fee option at enrollment will never incur a Membership Fee for returning an order.
- 8. Returning an order to It Works! will not automatically cancel the Loyal Customer's monthly autoshipment. To cancel an autoshipment the Loyal Customer can call the Customer Support number listed below or submit a support ticket in the Loyal Customer portal. All autoshipment cancellation requests must be completed at least two (2) business days prior to the autoshipment process date.
- 9. If only a portion of a stocked package (several products grouped under one item name/number) is returned, the full value of the item(s) kept will be deducted from the return order.
- 10. Once a returned order is received and inspected at the Returns Processing Center (usually within 10 business days), a refund will be processed to the credit card used to purchase the order. Depending on the credit card company, it may take an additional 2-10 business days after a refund is applied for monies to post to the Loyal Customer's account.
- 11. All returns must be accompanied with the original, or a copy of the original, packing slip.
- 12. To exchange products, Loyal Customers can submit a support ticket in their Loyal Customer portal within thirty (30) days of delivery to specify which product they would like to return and which products they would like to purchase in exchange. Exchange orders should be placed <u>prior</u> to Loyal Customer's returning their original items for refund to avoid interruption of their autoshipment services.

#### PRODUCTS MUST BE RETURNED TO:

IT WORKS MARKETING, INC. 4005 Newpoint Place Suite 200 Lawrenceville, GA 30043

**Customer Support:** 

https://itworks.com/contactus

## EXHIBIT 9

**Find** businesses, charities, category

<u>Home</u> > <u>Florida</u> > <u>Palmetto</u> > <u>Home Based Business Marketing</u> > IT Works! Global

Better Business Bureau®

Pacific Beach, CA

US 🗸

Search

Share Print

IT Works! Global **Not BBB** 

**Business Profile** 

Accredited Home Based Business Marketing

Headquarters Multi Location Business Find locations

## ▲ CURRENT ALERTS FOR THIS BUSINESS

### Pattern of Complaints: BBB has received a pattern of complaints from consumers alleging that after trying to cancel with the business, they continue to receive additional products.

Consumers also state that they have found additional charges being taken that the business has not informed them would be occurring. Complaints also allege ... Read More

## **Custom Rating Text:**

On April 24, 2020 FTC sent It Works Marketing, Inc. ("It Works!") a Warning letter Regarding Earnings Claims Related to Coronavirus Disease 2019 (COVID-19). Per the FTC on the business social media website at https://www.facebook.com/TheOfficialltWorks/, and by It Works! business opportunity participants or ... Read More

## ADDITIONAL BUSINESS INFORMATION

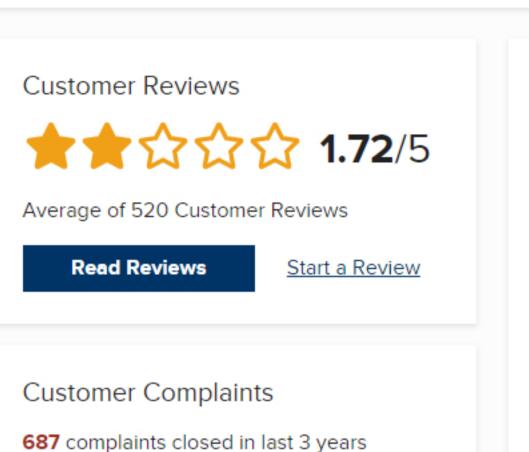
Additional Information: Loyal Customer Agreement

The Loyal Customer Agreement states that in order the get wholesale (discounted) pricing for life a Loyal Customer agrees to "fulfill the three-month minimum" purchase agreement." By completing your enrollment, you agree to the following: 1) Your credit card will be billed for the initial order and any subsequent orders. 2) B...Read More

## Contact Information

- 908 Riverside Dr
- Palmetto, FL 34221-5035 → Get Directions
- http://www.itworks.com
- **J** (941) 348-6650

O 6:30 AM - 8:00 PM ▼



**190** complaints closed in last 12 months

**Read Complaints** 

BBB Rating & Accreditation



THIS BUSINESS IS NOT BBB ACCREDITED

See all additional business information

Years in Business: 20

Reasons for BBB Rating

calculation of BBB Rating

Customer Reviews are not used in the

**Business Details** This is a multi-location business. Need to find a different location?

### Headquarters 908 Riverside Dr, Palmetto, FL 34221-5035

4/25/2011 BBB File Opened: Years in Business: 20

Business Started: 4/12/2001 Business Incorporated: 2/1/2011 in MI, USA Type of Entity: Corporation

## IT Works Marketing, Inc.

Alternate Business Name

Hours of Operation

### Primary **M:** 6:30 AM - 8:00 PM

T: 6:30 AM - 8:00 PM W: 6:30 AM - 8:00 PM

Th: 6:30 AM - 8:00 PM F: 6:30 AM - 8:00 PM

### **Sa:** 8:30 AM - 5:00 PM Su: 8:30 AM - 5:00 PM

Contact Information

Principal

Ms. Beth McDonald, Compliance Specialist

Other Contacts

Mr. Tim Seat. General Counsel

Mr. Mark B. Pentecost, President/CEO Mr. Douglas Nooney, Chief Compliance Officer

Ms. Cindy Pentecost, Secretary/Treasurer Mr. Jerry Ogle, CFO

Read More Business Details and See Alerts

# **Customer Complaints**

687 Customer Complaints

File a Complaint

Need to file a complaint? BBB is here to help. We'll guide you through the process. How BBB Processes Complaints and Reviews

File a Complaint

Most Recent Customer Complaint Complaint Type: Billing/Collection Issues

Status: Resolved ? 08/23/2021

I purchased a weight loss supplement from ItWorks. There's a three month supply requirement, or else one has to pay a \$50

subscription service, so I paid \$70.43 for one month on 12 Aug (incl. shipping & handling). I've used the product for 6 days. Each day I've been on it, I've been extremely tired & hungry, which has caused me to GAIN 6.4 lbs in six days. If I stay on this for 90 days, I'll be HEAVIER! I told the "friend" this evening that I want to cancel the autoship, & she said that I have to pay \$50 to cancel the autoship or order some other product from the company. I've already tried the coffees they sell, and they're repugnant, so I definitely don't want those. Nothing else they have interests me. I'm not trying to get a refund for the \$70.43. I tried the product & had the intention of following through on all three months, but it doesn't work for me, & I do not want any more of it. I'm giving lots of notice. Please allow me to cancel without penalty.... Read More

**Desired Outcome** Allow me to cancel without any further charges.

Read 686 More Complaints

## **Customer Reviews**

520 Customer Reviews

What do you think? Share your review. How BBB Processes Complaints and Reviews

Start a Review

Most Recent Customer Review Jessica W



08/31/2021

I couldn't cancel my auto ship because it said I would be charged 50\$. So I got charged the 40\$ for the package and it's going to an address that I no longer live at and have no access to the mail there. They won't do anything to help me and are saying I'm out the money unless the item is returned. How am I supposed to return an item I will never receive

# IT Works! Global Response

09/01/2021

Hello \*\*\*\*\*\*\*, We are sorry to hear about this matter. Our records show you contacted customer service on August 31, 2021, and they cancelled the autoship. Please be advised there is no membership fee as you completed the loyal customer agreement. Regarding your last order, please fill out the Lost Order Claim Form for customer service to review at https://lostorderclaim.myitworks.com/ . Sincerely, It Works!

Read 519 More Customer Reviews

# **Business Categories**

Home Based Business Marketing

# Local BBB

BBB of West Florida

More Info on Local BBB

# BBB Reports On

BBB reports on known marketplace practices.

See What BBB Reports On

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Information provided is accurate. However, BBB does not verify the accuracy of information provided by third parties, and does not guarantee the accuracy of any information in Business Profiles. BBB Business Profiles are provided solely to assist you in exercising your own best judgment. BBB asks third parties who publish complaints, reviews and/or responses on this website to affirm that the information provided is accurate. However, BBB does not verify the accuracy of information provided by third parties, and does not guarantee the accuracy of any information in Business Profiles. When considering complaint information, please take into account the company's size and volume of transactions, and understand that the nature of complaints and a firm's responses to them are often more important than the number of complaints. BBB Business Profiles generally cover a three-year reporting period. BBB Business Profiles are subject to change at any time. If you choose to do business with this business, please let the business

know that you contacted BBB for a BBB Business Profile. As a matter of policy, BBB does not endorse any product, service or business.

## For Consumers Search for a Business

Get a Quote

Start a Review File a Complaint BBB Scam Tracker File an Auto Warranty Complaint BBB Ad Truth Sign up for Scam Alerts Frequently Asked Questions (FAQ)

## For Businesses Search Business Profiles

Get Accredited

BBB EU Privacy Shield Get Your Business Listed

## **BBB Directory** Give.org

**About BBB** 

**BBB Institute for Marketplace Trust** International Association of Better **Business Bureaus** Contact BBB Business Partner Code Mission & Vision **BBB National Programs** 









**Hyperlinking Policy** more important than the number of complaints.

Terms of Use | Privacy Policy | Your Ad Choices | Trademarks |

BBB Institute for Marketplace Trust, Inc. All rights reserved. \*In Canada, trademark(s) of When considering complaint information, please take into account the company's size and volume of transactions, and understand that the nature of complaints and a firm's responses to them are often BBB Business Profiles generally cover a three-year reporting period. BBB Business Profiles are subject to change at any time. If you choose to do business with this business, please let the business

For Consumers

As a matter of policy, BBB does not endorse any product, service or business.

know that you contacted BBB for a BBB Business Profile.

Search for a Business Get a Quote Start a Review File a Complaint BBB Scam Tracker File an Auto Warranty Complaint BBB Ad Truth Sign up for Scam Alerts

## Search Business Profiles Get Accredited

For Businesses

BBB EU Privacy Shield Get Your Business Listed

## **BBB Directory** Give.org

**About BBB** 

BBB Institute for Marketplace Trust International Association of Better **Business Bureaus** Contact BBB Business Partner Code Mission & Vision **BBB National Programs** 





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## EXHIBIT 10

908 Riverside Dr. • Palmetto. FL 34221

#### It Works! Website Terms of Use

Please read these Terms of Use (the "Agreement") carefully before using this website. By accessing, browsing, or using the It Works! website located at www.itworks.com (the "Site"), and/or other It Works! sites that link to these Terms of Use including mobile applications, It Works! services and products, or any applications, including Distributor replicated websites, made available by It Works! (collectively the "Service"), you agree to be bound by this Agreement and all terms and conditions incorporated by reference. The Service is owned and/or operated and controlled by It Works Marketing, Inc. ("It Works!"). These Terms of Use affect your legal rights and obligations. If you do not agree to be bound by all of these terms and conditions, do not access or use the Service.

There may be times when we offer a special promotion or feature that has its own terms and conditions that apply in addition to these Terms of Use. In those cases, the terms specific to the special promotion or feature control with regard to that special promotion or feature to the extent there is a conflict with these Terms of Use.

<u>Notice Regarding Dispute Resolution</u>: These Terms of Use contain provisions that govern how claims you and we may have against each other are resolved (see Section 10 below). Unless you opt-out of arbitration: (a) you will only be permitted to pursue claims against us on an individual basis, not as part of any class or representative action or proceeding, and (b) you will only be permitted to seek relief (including monetary, injunctive, and declaratory relief) on an individual basis.

We may modify these terms and conditions of this Agreement from time to time. We will notify you of material changes to this Agreement by posting the revised Agreement on the Service at least thirty (30) days before the effective date. If you do not agree with the revised draft of this Agreement, you should discontinue your use of the Service prior to the time the revised Agreement takes effect. Your continued use of the Service after the new Agreement takes effect will mean that you accept those changes.

- 1. **Privacy Policy.** In connection with your use of the Service, please review our Privacy Policy, located at <a href="http://www.itworks.com/Legal/Privacy/">http://www.itworks.com/Legal/Privacy/</a> to understand how we use information we collect from you when you access, browse, or use the Service. The Privacy Policy is part of and is governed by these Terms of Use and by agreeing to these Terms of Use, you agree to be bound by the terms of the Privacy Policy and agree that we may use information collected from you in accordance with its terms.
- 2. Affirmative Representations Regarding Your Use of the Service. When you use the Service, you represent that: (a) you are an It Works! Distributor, associated with an It Works! Distributor, or a customer of It Works! or one of its Distributors; (b) you are 18 years of age or older or you are of sufficient legal age or otherwise have legal capacity to legally enter into these Terms of Use; (c) you will comply with all laws, rules, and regulations applicable to your use of the Service and your Contributions (defined in Section 4 below), including but not limited to, copyright laws; and (d) if you are using the Service on behalf of a legal entity, you represent that you are authorized to enter into an agreement on behalf of that legal entity.

#### 3. Member Accounts and Registration

You may be required to register with It Works! to access certain interactive portions of the Service. As a registered member you agree to: (i) provide true, accurate, current, and complete information about yourself as prompted by the Service's registration form (the "Registration Data"); (ii) maintain and promptly update the Registration Data; and (iii) comply with the rules governing Contributions in Section 4 below. It Works! prohibits the creation of, and you agree that you will not create, an account for anyone other than yourself.

As part of the registration process, you will be required to create a user ID and password. Only one user ID may be associated with your member account. You may not use a user name or email address that belongs to or is already being used by another person; that may be construed as impersonating another person; that violates the intellectual property or other

rights of any person; that is offensive; or that we reject for any other reason in our sole discretion. You will be responsible for maintaining the confidentiality of your user ID and password and you are responsible for any activity that occurs through your account. You further agree you will not sell, transfer, license, or assign your account, followers, username, or any account rights without the express written permission of It Works!.

#### 4. Rules Governing User Contributions; Prohibited Activities.

*User Contributions*. If you maintain an active member account with the Service, you may be able to submit comments and content to the Service (collectively, "Contributions"). When you make Contributions, you acknowledge and agree that those Contributions will be non-proprietary and non-confidential, may be made available to the general public, and may be used by It Works! without restriction. You grant to It Works! the worldwide, perpetual, royalty-free, irrevocable, nonexclusive right and license, sublicensable through multiple tiers, without compensation to you, to use, reproduce, distribute (through multiple tiers), adapt (including without limitation edit, modify, translate, and reformat), create derivative works of, transmit, publicly display, publicly perform, digitally perform, make, have made, sell, offer for sale and import all Contributions, in any media now known or hereafter developed, for any purpose whatsoever, commercial or otherwise. You are responsible for the content of, and any harm resulting from, Contributions you make on or through the Service. When making a Contribution, you represent and warrant that:

- you own or have sufficient rights to your Contributions;
- your Contribution does not violate, misappropriate, or infringe on the rights of any third party, including, without limitation, privacy rights, publicity rights, copyrights, trademark, and/or other intellectual property rights;
- you have fully complied with any third-party licenses relating to Contributions and shall pay all royalties, fees, and any other monies required to be paid in connection with Contributions that you post on or through the Service;
- you will not post Contributions that: (A) are defamatory, damaging, disruptive, unlawful, inappropriate, offensive, inaccurate, pornographic, vulgar, indecent, profane, hateful, racially or ethnically offensive, obscene, lewd, lascivious, filthy, threatening, excessively violent, harassing, or otherwise objectionable; (B) incite, encourage or threaten immediate physical harm against another, including but not limited to, Contributions that promote racism, bigotry, sexism, religious intolerance or harm against any group or individual; and (C) contain material that solicits personal information from anyone under the age of 13 or exploits anyone in a sexual or violent manner;
- you will not post Contributions that contain advertisements or solicit any person to buy or sell products or services; and
- you will not post Contributions that constitute, contain, install, or attempt to install or promote spyware, malware, or other computer code, whether on our or others' computers or equipment, designated to enable you or others to gather information about or monitor the on-line or other activities of another party.

**Prohibited Activities.** In addition to the obligations described in Section 6(a), you agree that in connection with your use of the Service, you will not:

- change, modify, adapt, or alter the Service or another website so as to falsely imply that it is associated with the Service
  or It Works!;
- use the Service for any unauthorized purpose including collecting usernames and/or email addresses by electronic or
  other means for the purpose of sending unsolicited email or other electronic communications, or engaging in
  unauthorized framing of, or linking to, the Service without our express written consent;
- transmit chain letters, bulk or junk email or interfere with, disrupt, or create an undue burden on the Service or the networks or services connected to the Service, including without limitation, hacking into the Service, or using the system to send unsolicited or commercial emails, bulletins, comments or other communications;
- impersonate any other person or entity, sell or let others use your profile or password, provide false or misleading identification or address information, or invade the privacy, or violate the personal or proprietary right, of any person or entity;
- post advertisements or solicitations for jobs or employment, or otherwise use the Service to hire any person to perform work;

- decompile, disassemble, modify, translate, adapt, reverse engineer, create derivative works from, or sublicense the Service, or any portion thereof;
- circumvent, disable, or otherwise interfere with security related features of the Service or features that prevent or restrict use or copying of any Materials (as defined in Section 8) or enforce limitations on use of the Service or the Materials on the Service;
- interfere or disrupt the Service or servers or networks connected to the Service, including by transmitting any worms, viruses, spyware, malware, or any other code of a destructive or disruptive nature. You may not inject content or code or otherwise alter or interfere with the way any It Works! page is rendered or displayed in a user's browser or device;
- create accounts with the Service through unauthorized means, including but not limited to, by using an automated device, script, bot, spider, crawler, or scraper; or
- attempt to restrict another user from using or enjoying the Service or encourage or facilitate violations of this Agreement or any other It Works! terms.
- 5. **Our Intellectual Property Rights.** Except for your Contributions and the Contributions of other users of the Service, the content on the Service ("Materials") and the trademarks, service marks, and logos contained on the Service are owned by or licensed to us and are subject to copyright and other intellectual property rights under United States and foreign laws and international conventions. The Service and the Materials are for your information and personal use only and not for commercial exploitation and you will not reproduce, modify, adapt, prepare derivative works based on, perform, display, publish, distribute, transmit, broadcast, sell, license or otherwise exploit the Materials. We reserve all rights in and to the Service and the Materials. If you download or print a copy of the Materials for your own personal use, you must retain all trademark, copyright, and other proprietary notices contained in and on the Materials.

#### 6. Our Management of the Service; User Misconduct

Our Right to Manage the Service. We reserve the right, but do not undertake the obligation to: (i) monitor or review the Service for violations of these Terms of Use and for compliance with our policies; (ii) report to law enforcement authorities and/or take legal action against anyone who violates these Terms of Use; (iii) refuse, restrict access to or the availability of, or remove, delete, edit or disable (to the extent technologically feasible) any Contribution or any portion thereof; (iv) manage the Service in a manner designed to protect our and third parties' rights and property or to facilitate the proper functioning of the Service; (v) screen our users or members, or attempt to verify the statements of our users or members and/or (vi) monitor disputes between you and other users or to terminate or block you and other users for violating these Terms of Use.

Interactions with other Users. You are solely responsible for your interactions with other users of the Service. Please note that there are risks that may arise when dealing with strangers, including persons who may be acting under false pretenses. Please choose carefully the information you post on the Service and that you give to other users of the Service. You are discouraged from publicly posting your telephone number or street address on the Service. Information posted to the Service by other users of the Service may be offensive, harmful or inaccurate, and in some cases may be mislabeled or deceptively labeled. You assume all risks associated with dealing with other users with whom you come in contact through the Service. Opinions and other statements included in users' Contributions do not represent the opinions or statements of It Works! and the posting of a Contribution on the Service does not constitute It Works'! support or endorsement of any opinions or statements expressed in the applicable Contribution.

Right to Terminate Users. WITHOUT LIMITING ANY OTHER PROVISION OF THESE TERMS OF USE, WE RESERVE THE RIGHT TO, IN OUR SOLE DISCRETION, AND WITHOUT NOTICE OR LIABILITY, DENY ACCESS TO AND USE OF THE SERVICE TO ANY PERSON FOR ANY REASON OR FOR NO REASON AT ALL, INCLUDING WITHOUT LIMITATION FOR BREACH OF ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN THESE TERMS OF USE, OR OF ANY APPLICABLE LAW OR REGULATION.

7. Third Party Sites. The Service may contain links to websites operated by third parties ("Third Party Sites"). We do not own

or operate the Third Party Sites, and we have not reviewed, and cannot review, all of the material, including goods or services, made available through Third Party Sites. The availability of these links on the Service does not represent, warrant, or imply that we endorse any Third Party Sites or any materials, opinions, goods, or services available on them. Third party materials accessed through or used by means of the Third Party Sites may also be protected by copyright and other intellectual property laws. These Terms of Use do not apply to Third Party Sites. Before visiting a Third Party Site through links provided on or through the Service, you should review the Third Party Site's terms and conditions and privacy policy.

#### 8. Warranty Disclaimer; Limitation on Liability

#### **Disclaimer of Warranties**

TO THE EXTENT PERMITTED BY LAW, THE SERVICE, INCLUDING, WITHOUT LIMITATION, ALL MATERIALS, IS PROVIDED ON AN "AS IS", "AS AVAILABLE" AND "WITH ALL FAULTS" BASIS. TO THE FULLEST EXTENT PERMISSIBLE BY LAW, NEITHER IT WORKS! NOR ITS PARENT COMPANY, AFFILIATES OR SUBSIDIARIES NOR ANY OF THEIR EMPLOYEES, MANAGERS, OFFICERS OR AGENTS (COLLECTIVELY, THE "IT WORKS! PARTIES") MAKE ANY REPRESENTATIONS OR WARRANTIES OR ENDORSEMENTS OF ANY KIND WHATSOEVER, EXPRESS OR IMPLIED, AS TO: (A) THE SERVICE; (B) THE Materials; (C) USER contributions; OR (D) SECURITY ASSOCIATED WITH THE TRANSMISSION OF INFORMATION TO IT WORKS! OR VIA THE SERVICE. IN ADDITION, THE IT WORKS! PARTIES HEREBY DISCLAIM ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, TITLE, CUSTOM, TRADE, QUIET ENJOYMENT, SYSTEM INTEGRATION AND FREEDOM FROM COMPUTER VIRUS.

TO THE EXTENT PERMITTED BY LAW, THE IT WORKS! PARTIES DO NOT REPRESENT OR WARRANT THAT THE SERVICE WILL BE ERROR-FREE OR UNINTERRUPTED; THAT DEFECTS WILL BE CORRECTED; OR THAT THE SERVICE OR THE SERVER THAT MAKES THE SERVICE AVAILABLE IS FREE FROM ANY HARMFUL COMPONENTS, INCLUDING, WITHOUT LIMITATION, VIRUSES. THE IT WORKS! PARTIES DO NOT MAKE ANY REPRESENTATIONS OR WARRANTIES THAT THE INFORMATION (INCLUDING ANY INSTRUCTIONS) ON THE SERVICE IS ACCURATE, COMPLETE, OR USEFUL. YOU ACKNOWLEDGE THAT YOUR USE OF THE SERVICE IS AT YOUR SOLE RISK. THE IT WORKS! PARTIES DO NOT WARRANT THAT YOUR USE OF THE SERVICE IS LAWFUL IN ANY PARTICULAR JURISDICTION, AND THE IT WORKS! PARTIES SPECIFICALLY DISCLAIM SUCH WARRANTIES.

PRODUCT SPECIFICATIONS AND OTHER INFORMATION HAVE EITHER BEEN PROVIDED BY IT WORKS! VENDORS OR COLLECTED FROM PUBLICLY AVAILABLE SOURCES. WHILE IT WORKS! MAKES EVERY EFFORT TO ENSURE THAT THE INFORMATION IN THE SERVICE IS ACCURATE, IT CAN MAKE NO REPRESENTATIONS OR WARRANTIES AS TO THE ACCURACY OR RELIABILITY OF ANY INFORMATION PROVIDED IN THE SERVICE. IT WORKS! MAKES NO WARRANTIES OR REPRESENTATIONS WHATSOEVER WITH REGARD TO ANY PRODUCT PROVIDED OR OFFERED BY IT WORKS! THROUGH ITS VENDORS, AND YOU ACKNOWLEDGE THAT ANY RELIANCE ON REPRESENTATIONS AND WARRANTIES OTHER THAN THOSE DESCRIBED ABOVE SHALL BE AT YOUR OWN RISK.

#### **Limitation of Liability**

TO THE EXTENT PERMITTED BY LAW, UNDER NO CIRCUMSTANCES WILL THE IT WORKS! PARTIES BE LIABLE TO YOU FOR ANY LOSS OR DAMAGES OF ANY KIND (INCLUDING, WITHOUT LIMITATION, FOR ANY DIRECT, INDIRECT, ECONOMIC, EXEMPLARY, SPECIAL, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES) THAT ARE DIRECTLY OR INDIRECTLY RELATED TO: (A) THE SERVICE; (B) THE Materials; (C) USER Contributions; (D) YOUR USE OF, INABILITY TO USE, OR THE PERFORMANCE OF THE SERVICE; (E) ANY ACTION TAKEN IN CONNECTION WITH AN INVESTIGATION BY THE IT WORKS! PARTIES OR LAW ENFORCEMENT AUTHORITIES REGARDING YOUR OR ANY OTHER PARTY'S USE OF THE SERVICE; (F) ANY ACTION TAKEN IN CONNECTION WITH COPYRIGHT OR OTHER INTELLECTUAL PROPERTY OWNERS; (G) ANY ERRORS OR OMISSIONS IN THE SERVICE'S OPERATION; OR (H) ANY DAMAGE TO ANY USER'S COMPUTER, MOBILE DEVICE, OR OTHER EQUIPMENT OR TECHNOLOGY INCLUDING, WITHOUT LIMITATION, DAMAGE FROM ANY SECURITY BREACH OR FROM ANY VIRUS, BUGS, TAMPERING, FRAUD, ERROR, OMISSION, INTERRUPTION, DEFECT, DELAY IN OPERATION OR TRANSMISSION, COMPUTER LINE OR NETWORK FAILURE OR ANY OTHER TECHNICAL OR OTHER MALFUNCTION, INCLUDING, WITHOUT

LIMITATION, DAMAGES FOR LOST PROFITS, LOSS OF GOODWILL, LOSS OF DATA, WORK STOPPAGE, ACCURACY OF RESULTS, OR COMPUTER FAILURE OR MALFUNCTION, EVEN IF FORESEEABLE OR EVEN IF THE IT WORKS! PARTIES HAVE BEEN ADVISED OF OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES, WHETHER IN AN ACTION OF CONTRACT, NEGLIGENCE, STRICT LIABILITY OR TORT (INCLUDING, WITHOUT LIMITATION, WHETHER CAUSED IN WHOLE OR IN PART BY NEGLIGENCE, ACTS OF GOD, TELECOMMUNICATIONS FAILURE, OR THEFT OR DESTRUCTION OF THE SERVICE). IN NO EVENT WILL THE IT WORKS! PARTIES BE LIABLE TO YOU OR ANYONE ELSE FOR LOSS, DAMAGE OR INJURY, INCLUDING, WITHOUT LIMITATION, DEATH OR PERSONAL INJURY. IN NO EVENT WILL THE IT WORKS! PARTIES TOTAL LIABILITY TO YOU FOR ALL DAMAGES, LOSSES OR CAUSES OR ACTION EXCEED ONE HUNDRED UNITED STATES DOLLARS (\$100.00). FOR NEW JERSEY RESIDENTS, THE LIMITATION ON LIABILITY IS INAPPLICABLE WHERE ATTORNEYS' FEES, COURT COSTS, OR OTHER DAMAGES ARE MANDATED BY STATUTE.

TO THE EXTENT PERMITTED BY LAW, YOU AGREE THAT IN THE EVENT YOU INCUR ANY DAMAGES, LOSSES OR INJURIES THAT ARISE OUT OF IT WORKS!' ACTS OR OMISSIONS, THE DAMAGES, IF ANY, CAUSED TO YOU ARE NOT IRREPARABLE OR SUFFICIENT TO ENTITLE YOU TO AN INJUNCTION PREVENTING ANY EXPLOITATION OF ANY WEBSITE, SERVICE, PROPERTY, PRODUCT OR OTHER CONTENT OWNED OR CONTROLLED BY THE IT WORKS! PARTIES, AND YOU WILL HAVE NO RIGHTS TO ENJOIN OR RESTRAIN THE DEVELOPMENT, PRODUCTION, DISTRIBUTION, ADVERTISING, EXHIBITION OR EXPLOITATION OF ANY WEBSITE, PROPERTY, PRODUCT, SERVICE, OR OTHER CONTENT OWNED OR CONTROLLED BY THE IT WORKS! PARTIES.

BY ACCESSING THE SERVICE, YOU UNDERSTAND THAT YOU MAY BE WAIVING RIGHTS WITH RESPECT TO CLAIMS THAT ARE AT THIS TIME UNKNOWN OR UNSUSPECTED.

9. Indemnification. To the extent permitted by law, you (and also any third party for whom you operate an account or activity on the Service) agree to defend (at It Works! request), indemnify and hold the It Works! Parties harmless from and against any claims, liabilities, damages, losses, and expenses, including without limitation, reasonable attorney's fees and costs, arising out of any of the following (including as a result of your direct activities on the Service or those conducted on your behalf): (i) your Contributions when used by It Works! as permitted hereunder; (ii) your breach or alleged breach of these Terms of Use; (iii) your violation of any third-party right, including without limitation, any intellectual property right, publicity, confidentiality, property or privacy right; (iv) your violation of any laws, rules, regulations, codes, statutes, ordinances or orders of any governmental and quasi-governmental authorities, including, without limitation, all regulatory, administrative and legislative authorities; or (v) any misrepresentation made by you. You will cooperate as fully required by It Works! in the defense of any claim. It Works! reserves the right to assume the exclusive defense and control of any matter subject to indemnification by you, and you will not in any event settle any claim without the prior written consent of It Works! You (and also any third party for whom you operate an account or activity on the Service) will not be required to indemnify and hold the It Works! Parties harmless from and against any claims, liabilities, damages, losses, or expenses resulting from It Works! own negligent conduct.

#### 10. Legal Disputes and Arbitration Agreement

- a. *Initial Dispute Resolution*. We are available by email at Privacy@itworks.com to address your concerns regarding use of the Service. Most concerns may be quickly resolved in this manner. You and It Works! agree to use best efforts to settle any dispute, claim, question, or disagreement directly through consultation and good faith negotiations which shall be a precondition to either party initiating a lawsuit or arbitration.
- b. AGREEMENT TO BINDING ARBITRATION. IF A SOLUTION IS NOT REACHED WITHIN A PERIOD OF THIRTY (30) DAYS FROM THE TIME INFORMAL DISPUTE RESOLUTION IS PURSUED PURSUANT TO THIS SECTION 10(a) ABOVE, THEN EITHER PARTY MAY INITIATE BINDING ARBITRATION. ALL CLAIMS ARISING OUT OF OR RELATING TO THESE TERMS OF USE (INCLUDING ITS FORMATION, PERFORMANCE AND BREACH), THE PARTIES' RELATIONSHIP WITH EACH OTHER AND/OR YOUR USE OF THE SERVICE SHALL BE FINALLY SETTLED BY BINDING ARBITRATION ADMINISTERED ON A CONFIDENTIAL BASIS BY THE AMERICAN ARBITRATION ASSOCIATION IN ACCORDANCE WITH THE PROVISIONS OF THE CONSUMER ARBITRATION RULES OF THE AMERICAN ARBITRATION ASSOCIATION (THE "AAA"), EXCLUDING ANY RULES OR

PROCEDURES GOVERNING OR PERMITTING CLASS ACTIONS. THE ARBITRATOR, AND NOT ANY FEDERAL, STATE OR LOCAL COURT OR AGENCY, SHALL HAVE EXCLUSIVE AUTHORITY TO RESOLVE ALL DISPUTES ARISING OUT OF OR RELATING TO THE INTERPRETATION, APPLICABILITY, ENFORCEABILITY OR FORMATION OF THESE TERMS OF USE, INCLUDING, BUT NOT LIMITED TO, ANY CLAIM THAT ALL OR ANY PART OF THESE TERMS OF USE IS VOID OR VOIDABLE. THE ARBITRATOR SHALL BE EMPOWERED TO GRANT WHATEVER RELIEF WOULD BE AVAILABLE IN A COURT UNDER LAW OR IN EQUITY. THE ARBITRATOR'S AWARD SHALL BE BINDING ON THE PARTIES AND MAY BE ENTERED AS A JUDGMENT IN ANY COURT OF COMPETENT JURISDICTION. THE INTERPRETATION AND ENFORCEMENT OF THESE TERMS OF USE SHALL BE SUBJECT TO THE FEDERAL ARBITRATION ACT.

THE PARTIES UNDERSTAND THAT THEY ARE WAIVING THEIR RIGHTS TO SUE IN COURT AND HAVE A JURY TRIAL. THEY FURTHER UNDERSTAND THAT, IN SOME INSTANCES, THE COSTS OF ARBITRATION COULD EXCEED THE COSTS OF LITIGATION AND THE RIGHT TO DISCOVERY MAY BE MORE LIMITED IN ARBITRATION THAN IN COURT.

THE AAA'S RULES GOVERNING THE ARBITRATION MAY BE ACCESSED AT WWW.ADR.ORG OR BY CALLING THE AAA AT 1.800.778.7879. TO THE EXTENT THE FILING FEE FOR THE ARBITRATION EXCEEDS THE COST OF FILING A LAWSUIT, WE WILL PAY THE ADDITIONAL COST. IF WE ARE REQUIRED TO PAY THE ADDITIONAL COST OF THE FILING FEES, YOU SHOULD SUBMIT A REQUEST FOR PAYMENT OF FEES TO AAA ALONG WITH YOUR FORM FOR INITIATING THE ARBITRATION, AND WE WILL MAKE ARRANGEMENTS TO PAY ALL NECESSARY FEES DIRECTLY TO AAA. THE ARBITRATION RULES ALSO PERMIT YOU TO RECOVER ATTORNEY'S FEES IN CERTAIN CIRCUMSTANCES.

- C. CLASS ACTION AND CLASS ARBITRATION WAIVER. YOU FURTHER AGREE THAT ANY ARBITRATION SHALL BE CONDUCTED IN YOUR RESPECTIVE INDIVIDUAL CAPACITY ONLY AND NOT AS A CLASS ACTION OR OTHER REPRESENTATIVE ACTION, AND YOU EXPRESSLY WAIVE YOUR RESPECTIVE RIGHT TO FILE A CLASS ACTION OR SEEK RELIEF ON A CLASS BASIS. IF ANY COURT OR ARBITRATOR DETERMINES THAT THE CLASS ACTION WAIVER SET FORTH IN THIS PARAGRAPH IS VOID OR UNENFORCEABLE FOR ANY REASON OR THAT AN ARBITRATION CAN PROCEED ON A CLASS BASIS, THEN THE ARBITRATION PROVISION SET FORTH ABOVE IN THIS SECTION 10 (b) SHALL BE DEEMED NULL AND VOID IN ITS ENTIRETY AND THE PARTIES SHALL BE DEEMED TO HAVE NOT AGREED TO ARBITRATE DISPUTES.
- d. **Exception Small Claims Court Claims**. Notwithstanding the parties' agreement to resolve all disputes through arbitration, either party may seek relief in a small claims court for disputes or claims within the scope of that court's jurisdiction.
- e. Arbitration and Class Action Waiver Opt-Out. You may opt-out and not be bound by the arbitration and class action waiver provisions set forth in this Section 10, (b), (c), and (d) by sending written notice of your decision to opt-out to It Works Marketing, Inc., Attn: Legal, 908 Riverside Drive, Palmetto, Florida 34221. The notice must be postmarked within thirty (30) days of registering to use the Service. Such notification must include: (i) your name; (ii) your email address and mailing address; and (iii) a clear statement that you do not wish to resolve disputes with us through arbitration or waive your ability to participate in a class action. If you do not notify us in accordance with this paragraph, you agree to be bound by the terms set forth in Section 2, including, without limitation, the arbitration and class-action waiver provisions, and also including such provisions in any modifications we make to these website Terms of Use after the date of your first acceptance.
- f. **Exclusive Venue for Litigation**. To the extent that the arbitration provisions set forth in this Section 10(b) do not apply, the parties agree that any litigation between them shall be filed exclusively in state or federal courts located in Manatee County, Florida, (except for small claims court actions which may be brought in the county where you reside). The parties expressly consent to exclusive jurisdiction in Florida for any litigation other than small claims court actions.
- g. **Applicable Law**. You agree that all matters relating to your use of the Service, including all disputes, will be governed by the laws of the United States and by the laws of the State of Florida, without regard to principles of conflict of laws.

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Survival. This Section 10 will survive the termination of any or all of your transactions with It Works!.

11. **Miscellaneous.** If any provision of these Terms of Use is held to be unlawful, void, or for any reason unenforceable, then that provision will be deemed severable from these Terms of Use and will not affect the validity and enforceability of any remaining provisions. No waiver by either party of any breach or default of these Terms of Use will be deemed to be a waiver of any preceding or subsequent breach or default. This Agreement does not, and shall not be construed to, create any partnership, joint venture, employer-employee, agency, or franchisor-franchisee relationship between you and It Works!. Any heading, caption or section title contained herein is inserted only as a matter of convenience, and in no way defines or explains any section or provision hereof. These Terms of Use constitute the entire agreement between you and It Works! and governs your use of the Service, superseding any prior agreements between you and It Works! Nou will not assign the Terms of Use or assign any rights or delegate any obligations hereunder, in whole or in part, whether voluntarily or by operation of law, without the prior written consent of It Works! Any purported assignment or delegation by you without the appropriate prior written consent of It Works! will be null and void. It Works! may assign these Terms of Use or any rights hereunder without your consent. These Terms of Use do not confer any third-party beneficiary rights.

March 2019